



Title: An evaluation of the implementation and practice of social prescribing

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An evaluation of the implementation and practice of social prescribing

By Julia Vera Pescheny



A thesis submitted to the University of Bedfordshire,
in fulfilment of the requirements
for the degree of Doctor of Philosophy

July 2019

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Abstract

It is a current policy priority in the UK to break down the traditional divide between primary care and community services, in order to deliver continuous, integrated, and need-driven care and to provide opportunities for health professionals to respond to the wider determinants of health more effectively. Social prescribing is an example of an approach in primary care that promotes partnership working between the health and community and voluntary sector. It provides health professionals with a non-medical referral option to address the non-medical needs of patients, determining their health and wellbeing. Given that social prescribing is increasingly implemented across the UK, it is a key priority for commissioners and service providers to understand the implementation, uptake and adherence, and potential outcomes of social prescribing, as well as the existing evidence base.

This study uses a mixed-methods design, reviewing previous evaluations on social prescribing to provide an overview of the evidence base. In addition, face-to-face semi-structured interviews were conducted with health professionals, navigators, service providers, managers, and decision-makers to explore the facilitators and barriers to the implementation of the social prescribing programme in Luton. Face-to-face, semi-structured interviews were also held with service users of the Luton programme, to explore the factors affecting uptake and adherence to social prescribing, as well as the patient outcomes from a service user perspective. Lastly, secondary data from the Luton programme was reviewed, to analyse the change in energy expenditure and mental wellbeing for service users after the programme.

The systematic literature review identified a range of service user outcomes and specific facilitators and barriers to the implementation of social prescribing, enabling increased and efficient access to available evidence. In addition, this study found that the implementation of the Luton programme was affected by operational processes, the evaluation process, communication, relationships, shared knowledge, and understanding among stakeholders, human resources, organisational readiness, and contextual factors. The uptake of social prescribing was affected by the trust in general practitioners, programme design, patient expectations, perceived need, and benefits, and fear of stigma of psychosocial problems. The support of navigators, the availability and accessibility of services, perceived benefits, and health and wellbeing of service users affected the adherence to the Luton programme. In addition, the study found that service users experienced improvements in their health related behaviours, mental wellbeing, and pain relief due to social prescribing. Lastly, the quantitative analysis showed that the Luton social prescribing programme has the potential to increase energy expenditure of participants and to activate sedentary patient groups. The

analysis also found a statistically significant improvement in mental wellbeing post-intervention.

Findings of this study contribute to the development of an evidence base for social prescribing and can support policy-makers, decision-makers, and providers to improve the implementation, uptake, and adherence for social prescribing in the future. In addition, the identified gaps in the evidence base and the limitations of this study can inform future research in this field.

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Table of Contents

1	Chapter 1: Introduction.....	1
1.1	Introduction.....	1
1.2	Social prescribing	2
1.2.1	A definition of social prescribing.....	2
1.2.2	The evidence base for social prescribing	4
1.3	Aim and objectives of the study	5
1.3.1	Aim.....	5
1.3.2	Objectives.....	5
1.4	Outline of the thesis	5
1.5	Chapter Summary	6
2	Chapter 2: Models of healthcare and social prescribing.....	7
2.1	Introduction.....	7
2.2	Healthcare in the UK	7
2.2.1	The biomedical approach	7
2.2.2	The biopsychosocial approach	10
2.3	The biopsychosocial approach in practice.....	13
2.3.1	Patient-centred care.....	13
2.3.2	Integrated care	13
2.4	Social prescribing	16
2.4.1	Policy context for social prescribing in the UK.....	16
2.4.2	Social prescribing delivery models in the UK	19
2.4.3	Potential challenges to the implementation and maintenance of social prescribing	22
2.5	Chapter summary.....	25
3	Chapter 3: The Luton social prescribing programme	26
3.1	Introduction.....	26
3.2	Demography of Luton.....	26
3.2.1	Health and life expectancy inequalities in Luton.....	26
3.2.2	Health and wellbeing trends in Luton	27
3.2.3	Informal carers in Luton	28
3.3	The Luton social prescribing model	29
3.3.1	Aims of the Luton social prescribing programme	29
3.3.2	Eligibility criteria	29
3.3.3	The Luton social prescribing pathway	30
3.3.4	Supporting information technology infrastructure.....	31

3.4	Chapter Summary	33
4	Chapter 4: Conceptual foundations	34
4.1	Introduction.....	34
4.2	The challenge of conceptualising integrated care.....	34
4.2.1	Theories originating from other disciplines	34
4.2.2	The Rainbow Model of integrated care.....	37
4.2.3	The Rainbow Model of integrated care as a theoretical underpinning for this study	42
4.3	Chapter summary.....	43
5	Chapter 5: Methodology	44
5.1	Introduction.....	44
5.2	Research aim and objectives.....	44
5.2.1	Research aim	44
5.2.2	Research objectives.....	44
5.3	Philosophical stances of research	44
5.3.1	Competing paradigms in social sciences	44
5.3.2	The positivist paradigm.....	45
5.3.3	The interpretive paradigm.....	48
5.3.4	Critical realism	51
5.4	Using a mixed methods research design.....	57
5.4.1	A convergent parallel mixed methods research design.....	58
5.5	Chapter summary.....	59
6	Chapter 6: Research methods	60
6.1	Introduction.....	60
6.2	Systematic review	60
6.2.1	Types of studies included in the systematic review	61
6.2.2	Types of participants included in the systematic review	61
6.2.3	Types of interventions included in the systematic review	61
6.2.4	Setting of interventions included in the systematic review.....	61
6.2.5	Outcomes included in the systematic review	61
6.2.6	Search methods for the identification of studies	62
6.2.7	Selection of studies	64
6.2.8	Data extraction and management.....	64
6.2.9	Data synthesis	64
6.2.10	Assessment of methodological quality	66
6.3	Qualitative methods.....	66

6.3.1	Sample selection	67
6.3.2	Recruitment.....	70
6.3.3	Data collection	74
6.3.4	Data preparation.....	79
6.3.5	Data analysis	79
6.3.6	Self-reflection.....	82
6.3.7	Rigour.....	85
6.4	Quantitative methods.....	89
6.4.1	Outcome measures	89
6.4.2	Data collection	90
6.4.3	Data preparation.....	90
6.4.4	Data analysis	94
6.4.5	Rigour.....	104
6.5	Ethics	105
6.5.1	Ethics approval.....	105
6.5.2	Ethical considerations in research.....	106
6.5.3	Ethical considerations in this study.....	107
6.6	Chapter summary.....	111
7	Chapter 7: Systematic review findings: Facilitators and barriers to the implementation of social prescribing in the UK	112
7.1	Introduction.....	112
7.2	Objective 1: Systematic literature review.....	112
7.2.1	Study selection process	112
7.2.2	Quality appraisal	113
7.2.3	Primary outcomes	116
7.2.4	Secondary outcomes	126
7.2.5	Summary of findings.....	134
7.3	Chapter summary.....	135
8	Chapter 8: Qualitative findings: Implementation, uptake, adherence, and outcomes of the Luton social prescribing programme	137
8.1	Introduction.....	137
8.2	Objective 2: Facilitators and barriers to the implementation of the Luton social prescribing programme.....	137
8.2.1	Participants.....	137
8.2.2	Findings.....	140
8.2.3	Summary of findings.....	167

8.3	Objective 3: Patient uptake and service user adherence to the Luton social prescribing programme.....	168
8.3.1	Participants.....	168
8.3.2	Findings.....	170
8.3.3	Summary of findings.....	188
8.4	Objective 4: Service user outcomes.....	189
8.4.1	Participants.....	189
8.4.2	Findings.....	189
8.4.3	Summary of findings.....	200
8.5	Chapter summary.....	200
9	Chapter 9: Quantitative results: Service user outcomes of the Luton social prescribing programme.....	201
9.1	Introduction.....	201
9.2	Objective 4: Service user outcomes.....	201
9.2.1	Descriptive analysis	201
9.2.2	Mental wellbeing: Skew-Normal regression.....	208
9.2.3	Energy expenditure: Bayesian zero-inflated negative binomial model	208
9.2.4	Summary of results	216
9.3	Chapter summary.....	217
10	Chapter 10: Discussion	218
10.1	Introduction	218
10.2	Discussion of objective 1	218
10.2.1	Primary outcome: Facilitators and barriers to the implementation of social prescribing in the UK.....	219
10.2.2	Secondary outcome: The impact of social prescribing on service users	222
10.3	Discussion of objective 2	225
10.4	Discussion of objective 3	229
10.5	Discussion of objective 4	233
10.5.1	Qualitative findings.....	234
10.5.2	Quantitative results	236
10.6	Study limitations	240
10.7	Chapter summary	243
11	Chapter 11: Conclusion.....	244
11.1	Introduction	244
11.2	Implementation and practice of SP	244
11.3	Evaluation of the Luton SP pilot.....	247

11.4	Strength and limitations of practice-based research.....	248
11.4.1	The Luton SP pilot.....	248
11.4.2	Outcome measures.....	249
11.4.3	Transferability of findings	251
11.5	Contribution to the field	252
11.5.1	Theoretically	252
11.5.2	Methodologically	252
11.5.3	Policy and planning	253
11.6	Recommendations	253
11.6.1	For policy and practice	253
11.6.2	For research.....	255
11.6.3	For education	258
12	Appendices.....	259
13	Bibliography.....	307

List of Tables

Table 1: Definitions of integrated care and primary care	39
Table 2: Inclusion and exclusion criteria for the service user sample	69
Table 3: Issues of rigour in qualitative research	87
Table 4: Definitions of terms used in Table 3	88
Table 5: Representation of the initially included variables in the database and their type	91
Table 6: Final list of variables included in the analysis.....	94
Table 7: Overview of the similarities and differences between frequentist and Bayesian statistics (Kirkwood and Sterne, 2003; Van de Schoot <i>et al.</i> , 2014)	101
Table 8: Issues of rigour in the quantitative study.....	105
Table 9: Summary of quality scores for each included study calculated using the MMAT-V 2011	115
Table 10: GP demographics (N=3).....	138
Table 11: Navigator demographics (N=4).....	138
Table 12: Service provider characteristics (N=6).....	139
Table 13: Service user characteristics.....	168
Table 14: Reasons for referral, type and number of referred services, and status at the point of the interview for service users	169
Table 15: Socio-demographic characteristics of referred patients (N=448) and proportions of missing data	201
Table 16: Referrals by GPs to navigator 1, 2, and 3, absolute number (N) and percentage (%)	202
Table 17: Available data on mental wellbeing pre- and post-intervention (N=448).....	203
Table 18: Socio-demographic characteristics of sample (N=68) for baseline and post- intervention data collected with the SWEMWBS and proportions of missing data.....	203
Table 19: Socio-demographic characteristics of sample (N=63) included in the final analysis of the SWEMWBS data.....	203
Table 20: Mean SWEMWBS scores pre and post intervention (N=63).....	204
Table 21: Baseline and post-intervention mean SWEMWBS scores by sex.....	206
Table 22: Baseline and post-intervention mean SWEMWBS scores by working status	206
Table 23: Baseline and post-intervention mean SWEMWBS scores by age	206
Table 24: Available data on energy expenditure pre- and post-intervention (N=448).....	207
Table 25: Socio-demographic characteristics of sample (N=186) for baseline data collected with the IPAQ-SF and proportions of missing data.....	207
Table 26: Socio-demographic characteristics of sample (N=146) included in the final analysis of IPAQ-SF data (i.e., with complete covariate and baseline data).....	208
Table 27: SN regression model results (N=63)	208

Table 28: Summary of results for Walking MET scores	210
Table 29: Summary of results for Moderate MET scores	212
Table 30: Summary of results for Vigorous MET scores	214
Table 31: Summary of results for Total MET scores	216
Table 32: Identified themes by service user related, programme related, and contextual factors	230
Table 33: Quantitative outcome measures used in included studies to measure service user outcomes and reported results	260
Table 34: Results of the Mixed Methods Appraisal Tool (MMAT) used for the quality appraisal of included studies	263
Table 35: Reported ethnicities of service users referred to the Luton social prescribing programme (secondary data)	300
Table 36: Reported reasons for referrals to the Luton social prescribing programme (secondary data)	301
Table 37: Reported barriers to adherence to the social prescribing programme (secondary data)	302

List of Figures

Figure 1: The NHS Outcome Framework 2015/16 (Department of Health, 2014).....	19
Figure 2: Map of Luton (Public Health England, 2018).....	26
Figure 3: Summary of Luton social prescribing pathway	31
Figure 4: The use of the activity card in the Luton SP programme (Luton Borough Council, 2015b)	32
Figure 5: The revised RMIC (Valentijn, 2016)	37
Figure 6: Hierarchy of evidence for questions about the effectiveness of an intervention or treatment (Akobeng, 2005)	46
Figure 7: The stratified Ontology of critical realism (Zachariadis, Scott and Barrett, 2013)..	52
Figure 8: Outline of the convergent parallel mixed methods design used in the present study	59
Figure 9: Adapted study selection flow diagram based on PRISMA (Moher <i>et al.</i> , 2009b).	113
Figure 10: Histogram of the SWEMWBS difference score distribution (N=63)	205
Figure 11: Box and whisker plot of the SWEMWBS difference score distribution (N=63).	205
Figure 12: The interrelationship between identified factors influencing the implementation of SP programmes (Objective 1).....	220
Figure 13: The interrelationship between identified factors influencing the implementation of SP programmes (Objective 2).....	226
Figure 14: The revised RMIC (Valentijn, 2016) placed in the implementation context.....	245
Figure 15: Key mechanism that triggers successful implementation and delivery of SP	246
Figure 16: Key mechanism that triggers patient uptake of SP when referred by GPs	246
Figure 17: Key mechanism that triggers service user adherence and behaviour change	247
Figure 18: Key mechanism that triggers adherence and positive service user outcomes.....	247
Figure 19: Histogram of Walking MET minutes/week difference score distribution (N=52)	303
Figure 20: Box and whisker plot of Walking MET minutes/week difference score distribution (N=52).....	303
Figure 21: Histogram of Moderate MET minutes/week difference score distribution (N=52)	304
Figure 22: Box and whisker plot of Moderate MET minutes/week difference score distribution (N=52)	304
Figure 23: Histogram of Vigorous MET minutes/week difference score distribution (N=52)	305
Figure 24: Box and whisker plot of Vigorous MET minutes/week difference score distribution (N=52).....	305
Figure 25: Histogram of Total MET minutes/week difference score distribution (N=52)....	306

Figure 26: Box and whisker plot of Total MET minutes/week difference score distribution (N=52).....	306
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List of abbreviations

Abbreviation	Meaning
A&E	Accident and Emergency
ASSIA	Applied Social Sciences Index & Abstracts
BME	Black and Minority Ethnic
CAS	Complex Adaptive System
CCG	Clinical Commissioning Group
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CORE-OM	Clinical Outcomes in Routine Evaluation-Outcomes Measure
CVD	Cardiovascular disease
GAD7	7-item Generalised Anxiety Disorder
GHQ-12	General Health Questionnaire-12
GP	General practitioner
GSE	General self-efficacy
HADS	Hospital Anxiety & Depression Scale
HMIC	Health Management Information Consortium
IAPT	Improving Access to Psychological Therapies
IMD	Index of Multiple Deprivation
IPAQ	International Physical Activity Questionnaire
IPAQ-SF	International Physical Activity Questionnaire Short Form
IT	Information technology
LBC	Luton Borough Council
LTC	Long term condition
MET	Metabolic equivalent
MMAT-V 2011	Mixed Methods Appraisal Tool Version 2011
MRC	Medical Research Council
MSR	Mixed studies review
MYMOP	Measure Yourself Medical Outcome Profile
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
PCT	Primary care trust
PHQ9	9-item Patient Health Questionnaire
PPI	Posterior probability interval
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RCT	Randomised control trial
RMIC	Rainbow Model of Integrated Care
SN	Skew-Normal
SP	Social prescribing
SPSS	Statistical Package for Social Sciences
STP	Sustainable Transformation Plans
SWEMWBS	Short Warwick-Edinburgh mental wellbeing scale
T2DM	Type 2 diabetes mellitus
UK	United Kingdom
US	United States

Abbreviation	Meaning
WEMWBS	Warwick-Edinburgh mental wellbeing scale
WHO	World Health Organisation
WSAS	Work and Social Adjustment Scale

1 Chapter 1: Introduction

1.1 Introduction

The population in the United Kingdom (UK) is growing and the proportion and absolute numbers of older people are expected to increase markedly in the coming decades (Office for National Statistics, 2015). The greatest growth is estimated in the number of people aged 85 years or older, who are the most intensive users of health and social care (Department of Health, 2012; NHS England, 2013). The probability of having a long-term condition (LTC) and multiple LTCs increases with age (Department of Health, 2008). LTCs are defined as conditions that cannot, at present, be cured but can be controlled by secondary prevention, medication, and other therapies (Department of Health, 2012). Examples of prevalent LTCs in the UK include: Coronary heart disease, heart failure, hypertension, diabetes, chronic obstructive pulmonary disease (COPD), schizophrenia, and depression (Department of Health, 2008). Due to an aging population, it is estimated that over the next decades the number of people with (multiple) LTCs will rise markedly in the UK (Department of Health, 2008, 2012). Therefore, health and social care systems need to be responsive to meet the needs of chronic patients and consider the effects on the future demands on resources (Department of Health, 2008; NHS England, 2014).

Peoples' health and wellbeing is determined by a complex interaction between genetics, biological, lifestyle, psychological, social, and environmental factors (Marmot *et al.*, 2010; Farre and Rapley, 2017). Psychosocial factors include emotional, social, and psychological factors, such as social isolation, low self-esteem, debt, and housing issues, that can impact on peoples' mental and physical health, wellbeing, and self-care (Marmot *et al.*, 2010; Kilgariff-Foster and O'Cathain, 2015). There is strong evidence that social support and psychological distress have an effect on adherence to self-care behaviour, glycaemic control, and health outcomes in individuals diagnosed with type 2 diabetes (Egede and Dismuke, 2012; Williams *et al.*, 2013; Smalls *et al.*, 2015; Walker, Smalls and Egede, 2015). Furthermore, a study by Sharon *et al.* (2014) found a significant association between social determinants of health and cardiovascular health. Social determinants of health are defined as conditions in which people are born, grow, work, and live that shape their health and wellbeing (Marmot *et al.*, 2010). In addition to the social determinants of health, biological, and psychosocial factors, the lifestyle choices of individuals influence their health and wellbeing, too (Rossen *et al.*, 2015). There is strong evidence that regular physical activity, for example, reduces the risk of the development of chronic conditions, such as cardiovascular disease (CVD), type 2 diabetes, and cancer (Booth, Roberts and Laye, 2012; Durstine *et al.*, 2013; Marques *et al.*, 2018). In addition to primary prevention, physical activity improves quality of life and plays an important role in secondary prevention of chronic conditions by reducing the impact of the

disease, slowing its progress, and preventing recurrence (Karmisholt and Gotzsche, 2005; Durstine *et al.*, 2013; Alves *et al.*, 2016). The evidence in this section demonstrates that in addition to biological factors, the wider determinants of health play an important role for an individuals' health, wellbeing, as well as primary and secondary prevention, and the management of chronic conditions.

In the UK, primary care in the National Health Service (NHS) offers people a first-point-of access to advice, diagnosis, and treatment (Smith *et al.*, 2013a). Traditionally, general practice in the UK has been dominated by an individualistic and medicalised system of primary care, focusing on disease and medical treatment rather than prevention, health promotion, and the wider determinants of health (Peckham, Hann and Boyce, 2011). However, it is clear that disease oriented and fragmented delivery of health services can no longer meet the complex needs of people with (multiple) chronic conditions (NHS England, 2014; Eaton, Roberts and Turner, 2015). Previous research found that GPs often feel unable to manage the complex psychosocial needs of patients because of time constraints, a high workload, and little up-to-date knowledge of local non-medical services (Zantinge *et al.*, 2005; Brandling and House, 2009; Peckham, Hann and Boyce, 2011; Kimberlee *et al.*, 2014; Bertotti *et al.*, 2017). Thus, the traditional boundaries between hospitals, health care, and third sector organisations (including charities, voluntary, and community organisations) need to be dissolved to provide personalised and coordinated health services around the needs of patients (NHS England, 2014). Partnerships between the health sector and third sector organisations are important, as the NHS do not has the resources to respond to non-medical problems such as social isolation, housing issues, and low self-esteem alone (Cawston, 2011; NHS England, 2014; Charles *et al.*, 2018). In response to the need of a more integrated delivery system, there have been several attempts to introduce the integration of the health and third sector over the past years in the UK (South *et al.*, 2008; Shaw, Rosen and Rumbold, 2011; Carnes *et al.*, 2017; NHS, 2017). Social prescribing (SP) is an example of a model increasingly implemented in the UK to bridge the gap between primary care and third sector organisations (Bickerdike *et al.*, 2017).

1.2 Social prescribing

1.2.1 A definition of social prescribing

To date there is no standardised definition of SP (Carnes *et al.*, 2017). In recent years this term has emerged as a means of linking individuals with sources of support within the third sector, with the aim to improve personal wellbeing and health (Carnes *et al.*, 2017). Increasingly, SP is identified as a model with the potential to improve patient care, improve population health, reduce health resource use in the NHS, and promote sustainability of

general practice (Husk *et al.*, 2016; Bertotti *et al.*, 2017; Bickerdike *et al.*, 2017). However, as reflected in the lack of a widely agreed definition, there is no single SP model, as the aims, delivery models (including referral routes and pathways), source and duration of funding, model of commissioning, geographical coverage, and the breadth of offered activities can vary between SP schemes (Dayson, 2017; Woodall *et al.*, 2018). To conceptualise the different SP models, Kimberlee (2015) has arranged SP models into signposting, light, medium, and holistic. The features of each of these four models will be discussed in more detail in Chapter 2 of this thesis. Besides the wide range of different SP models in the UK, those based in general practice and involving a navigator seem to be dominant and increasingly implemented across the UK (Polley *et al.*, 2016; Bickerdike *et al.*, 2017; Dayson, 2017). Navigators are also referred to as ‘facilitators’, ‘link workers’, and ‘coordinators’ in the literature (Kimberlee, 2015; Bertotti *et al.*, 2017; Woodall *et al.*, 2018). In this thesis, the term ‘navigator’ will be used.

The pathway in this dominant SP model starts with a referral from general practitioners (GPs) or other frontline healthcare professionals to a navigator. Thus, it provides healthcare professionals with a non-medical referral option, which can operate alongside medical treatment, to respond more effectively to the wider determinants of health and non-medical needs of patients (Bickerdike *et al.*, 2017). Following the referral, navigators arrange an appointment with patients (usually held face-to-face in the surgery they are based in) to discuss their non-medical needs (e.g. social, practical, or emotional needs) in detail. Commonly navigators can refer service users to an extensive range of services, predominantly provided by third sector organisations, to meet their identified needs, promote patient empowerment, and health and wellbeing improvements (Bertotti *et al.*, 2017; Bickerdike *et al.*, 2017). Examples of such services and activities include art therapy, walking and reading groups, exercise classes, nature-based activities, volunteering, legal advice, and support with employment, debt, and housing (Moffatt *et al.*, 2017). The research in this thesis is based upon the described dominant SP model, which is based in general practice and involves navigators. The primary and secondary study will be based on a local example in the East of England, the Luton SP programme. Luton, where this study takes place, is ranked as one of the most deprived areas in the UK (Research and Geospatial Information Team, 2015). Given the high prevalence of chronic conditions and poor wellbeing linked to poverty and psychosocial needs, the SP programme has the potential to address the non-medical needs and improve the health and wellbeing of Luton’s population (Luton Borough Council, 2015a; Public Health England, 2018).

1.2.2 The evidence base for social prescribing

Besides the increasing policy attention and implementation of SP models in recent years in the UK, the evidence base for SP is limited (Woodall *et al.*, 2018). Many local SP programmes are not evaluated, which may be explained by a minor interest in ‘scientific’ outcomes of the implementation of local interventions or limited budgets for research and evaluation (Thomson, Camic and Chatterjee, 2015; Pilkington, Loef and Polley, 2017; Woodall *et al.*, 2018). Although exercise-on-referral (Pavey *et al.*, 2012) and art-on-prescription schemes (Bungay and Clift, 2010; Stickley, 2010), which fit the concept of SP, were evaluated and the results published previously, very little evidence on SP was published in academic journals at the beginning of this PhD study in 2015. A weakness of many literature reviews on SP is that they are not systematic and do include multiple SP models with different referral routes and pathways (Centre for Reviews and Dissemination, 2015; Kinsella, 2015; Thomson, Camic and Chatterjee, 2015). However, it is important to differentiate between different SP programmes, as differences in delivery models, funding sources, and geographical coverage can have an impact on the implementation process and outcomes (Husk *et al.*, 2016; Dayson, 2017). Moreover, previous research found that within evaluated SP schemes, studies often lack methodological rigour and transparent reporting (Centre for Reviews and Dissemination, 2015; Kinsella, 2015; Thomson, Camic and Chatterjee, 2015). Given the little good quality evidence on SP, the importance of rigorous evaluations of local SP interventions and transparent reporting of research methods and results is increasingly stressed in the literature (White, Kinsella and South, 2010; Centre for Reviews and Dissemination, 2015; Kilgarriff-Foster and O’Cathain, 2015; Thomson, Camic and Chatterjee, 2015; Bickerdike *et al.*, 2017).

However, whereas most studies focused on outcome evaluations, little is known about the challenges of implementing SP schemes in practice (Bertotti *et al.*, 2017). The implementation of a SP intervention is likely to influence the delivery and operation of the intervention, which in turn influences the outcomes and long-term sustainability (Moore *et al.*, 2014; Bertotti *et al.*, 2017). Thus, it is crucial to develop a good understanding of factors that hinder and facilitate the implementation of specific SP programmes (Husk *et al.*, 2016; Bertotti *et al.*, 2017; Skivington *et al.*, 2018). Moreover, exploring factors affecting the implementation of SP schemes would be particularly useful to aid decision-makers, commissioners, and providers in the development and more effective implementation of SP schemes and would enable stakeholders to learn from previous experiences (Bertotti *et al.*, 2017). There is evidence that the end users’ perspectives and views influence the implementation and delivery of a health intervention, too, as without their uptake and adherence, an intervention cannot be delivered (Chaudoir, Dugan and Barr, 2013).

Nevertheless, there is a lack of studies exploring factors affecting initial participation of patients (uptake) and continuous participation (adherence) in SP schemes (Kimberlee, 2013; Husk *et al.*, 2016). The consequences of non-uptake and non-adherence may include preventable suffering, suboptimal outcomes, increases in health inequalities, and wasted resources (Gidlow *et al.*, 2007; Barello, Graffigna and Vegni, 2012). The identification of factors hindering uptake and adherence could support the refinement of SP programmes to enhance uptake and adherence, as well as optimising investment (Barello, Graffigna and Vegni, 2012; Pavey *et al.*, 2012).

This study seeks to address the identified knowledge and evidence gaps by using a mixed-methods approach to identify and synthesise available evidence on the implementation and service user outcomes of SP schemes in the UK. In addition, it seeks to examine the service user outcomes and to explore factors affecting the implementation, patient uptake, and adherence for a local example in the East of England, the Luton SP programme. The combination of a national literature review and the robust evaluation of a local SP programme provides added value through the comparison of results and provision of a national embedding of local research.

1.3 Aim and objectives of the study

1.3.1 Aim

To develop a framework of knowledge to advance the implementation, practice, and evaluation of SP.

1.3.2 Objectives

The objectives of this study were:

1. To identify and synthesise evidence on:
 - Factors that facilitate and hinder the implementation of SP programmes in the UK
 - The impact of SP on service users in the UK
2. To identify the factors that facilitate and hinder the implementation of the Luton SP programme
3. To explore the factors that affect patient uptake and service user adherence to the Luton SP programme
4. To assess and explore service user outcomes of the Luton SP programme

1.4 Outline of the thesis

This thesis is presented in 13 chapters. Chapter 1 presents the background, context, aims, and objectives for this study. Chapter 2 presents the different models and approaches of

healthcare, with a particular focus on the biopsychosocial approach and how it can be applied in practice. It moves on to discuss SP as an example of an intervention based on the biopsychosocial approach and discusses the national policy context in relation to SP, as well as the different delivery models and potential challenges to implementation of SP. Chapter 3 discusses the study context (Luton) for the primary research and the Luton SP model in more detail. Chapter 4 discusses the conceptual foundations of this work. It highlights the challenges of conceptualising integrated care initiatives, such as SP, and explains why the Rainbow Model of integrated care provides an appropriate theoretical underpinning for this work. Chapter 5 discusses and compares the different research paradigms and provides a rationale for applying a critical realist stance and using the chosen methodology of a mixed-methods design. Chapter 6 outlines the research methods used to meet the four objectives of this study. Chapter 7 to Chapter 9 comprise the findings and results from the systematic review, qualitative, and quantitative studies, respectively. Chapter 10 discusses the results/findings and limitations of the study and Chapter 11 concludes the thesis with presenting the contribution to the field and recommendations for future research, education, and policy and practice. Chapter twelve presents the Appendices and Chapter thirteen the bibliography.

1.5 Chapter Summary

This chapter has presented the background to the study and outlined the important gaps in the evidence base for SP. It then presented the aim and objectives of this study. The findings from this research will provide an understanding of possible barriers and facilitators to implementation and factors affecting patient uptake and adherence. In addition, this study will provide evidence on the potential service user outcomes of SP. Findings from this research will contribute towards the development and implementation of SP schemes and can inform commissioning and future research in this field.

2 Chapter 2: Models of healthcare and social prescribing

2.1 Introduction

Chapter 1 highlighted that the prevalence of multiple chronic conditions is rising in the UK and that the NHS needs to change to meet the medical and non-medical needs of patients, which influence their health and wellbeing. In addition, the concept of SP programmes and their potential to improve the integration of health and social services was explored. This chapter presents the developments in healthcare approaches and then discusses the elements of applying a biopsychosocial approach to healthcare in practice and how SP is related to this approach. The last section of this chapter discusses the national policy context in relation to SP, different delivery models of SP, and the potential challenges to the implementation of SP in the UK.

2.2 Healthcare in the UK

2.2.1 The biomedical approach

The delivery of healthcare is influenced by cultural and professional models of disease (Wade and Halligan, 2004). By the end of the 19th century, the miasma theory was largely replaced by the germ theory of disease (McKeown, 2009). The miasma theory was based on the assumption that the major causes of disease are environmental (from soil, water, and air), thus in the 18th and early 19th century the improvement of living conditions was the focus to improve health (Loomis and Wing, 1990; McKeown, 2009). The germ theory was based on the assumption that a proximate, singular microbial causes disease (Egger, 2012). This movement was based on scientific advances in bacteriology, chemistry, medicine, and epidemiology supported by the French chemist and microbiologist Louis Pasteur, the English surgeon Joseph Lister, the German physician Robert Koch, and others (McKeown, 2009). The increasing dominance of the germ theory shaped the medical model in the UK and other western countries. Consequently, the biomedical model of illness dominate healthcare since the 20th century (Wade and Halligan, 2004; Busfield, 2010). George Engel (1977) describes the biomedical model in 1977 as follows:

‘The dominant model of disease today is biomedical, with molecular biology its basic scientific discipline. It assumes diseases to be fully accounted for by deviations from the norm of measurable biological (somatic) variables.’ (Engel, 1977, p.130)

The aim of treatment in the biomedical model is to target underlying biological dysfunction and the biomedical or neurophysiological disease processes without harming the organism (Engel, 1977; Deacon, 2013). Therefore, the focus in medicine and public health in the 20th

century was on biochemical deviations informing diagnosis, treatment and prevention (Stineman and Streim, 2010). Anything that could not be explained by molecular or cellular processes and objectively verified was largely ignored in clinical practice. Therefore, the traditional biomedical model excludes social, psychological, and behavioural dimensions of illness (Engel, 1977). Hence, healthcare delivery in this model is based around medical practitioners alone (Irvine *et al.*, 2002).

The underlying beliefs of the biomedical model include (Wade and Halligan, 2004):

- Underlying abnormalities within the body (usually in the functioning or structure of specific organs), referred to as disease, cause illness and symptoms
- Health is the absence of disease
- The patient has little or no responsibility for the presence or cause of the illness
- The patient is a passive recipient of treatment
- Mental health problems are separate and unrelated to physical health problems

In the disease-oriented biomedical model, the primary aim of research was to uncover the biological risk factors, causes of disease, and outcomes of treatment (Deacon, 2013). However, Goldfried and Wolfe (1998) argued that the dominance of the biomedical model led to the medicalisation of outcome research. This meant that health services and interventions needed to be evaluated in terms of their efficacy in reducing disease and symptoms (Goldfried and Wolfe, 1998). Thus, experimental research designs, such as a randomised control trial (RCT), were recognised as the ‘gold standard’ to estimate the causal effects of treatments on pre-defined outcomes (Goldfried and Wolfe, 1998; Shadish, Cook and Campbell, 2002). Today, RCTs and experimental methods are still considered to be the gold standard for producing robust evidence on cause and effect relationships, hence clinical effectiveness, in medicine and public health (Marchal *et al.*, 2013).

Strength and limitations of the biomedical approach

The biomedical approach to disease has utility in many areas of healthcare (Engel, 1977; Borrell-Carrió, Suchman and Epstein, 2004; Rosenbaum and Stewart, 2004; Stineman and Streim, 2010). Advances in medical technology were driven by biomedical concepts and fostered important advances in medicine, for example the diagnosis of bacterial agents in infectious diseases (Rosenbaum and Stewart, 2004; Stineman and Streim, 2010). Pharmaceutical treatment of bacterial infections, for example with penicillin, immunization, and pasteurization contributed to the reduction of fatal early-life diseases (Egger, 2012).

Thus, the major role of public health and medicine were infectious disease prevention and control in the 20th century (Egger, 2012). Consequently, life expectancy increased considerably between the beginning of the 20th and 21st century, from less than 50 years of age to over 75 years of age (McKeown, 2009). Hence, the biomedical model contributed to the ‘epidemiologic transition’ in the 20th century, related to changes in patterns of mortality, increasing life expectancy, and reordering of the major causes of death (McKeown, 2009). Infectious disease pandemics were replaced by chronic health conditions as major causes of death and infectious agents were replaced by anthropogenic causes as the major contributor to multimorbidity and mortality (McKeown, 2009; Egger, 2012). Thus, the ‘epidemiologic transition’ required a shift in the attention of public health and medicine towards chronic disease prevention and control (Engel, 1977; Rosenbaum and Stewart, 2004; McKeown, 2009). In addition, the traditional boundaries among medical specialists appear to be more inadequate in the prevention and management of multiple chronic conditions that require an integrated approach (Fava, Cosci and Sonino, 2017).

George Engel, an internist and psychiatrist, has criticised the biomedical model for its excessively narrow and limited biomedical focus, for its disempowerment of patients, and exclusion of their subjective experience, and wider determinants of health and illness (Borrell-Carrió, Suchman and Epstein, 2004). While the term ‘disease’ used in the biomedical model has a strictly physiologically based definition (e.g. organic malfunction), the term ‘illness’ includes both the human experience of ‘ill health’ and the objective (physiological) element (Farre and Rapley, 2017). Engel’s main criticism of the biomedical model was that it embraces reductionism, the philosophical view that complex clinical phenomena can be explained by a single primary principle (e.g. genetics) (Engel, 1977; Fava and Sonino, 2017). In the context of the biomedical model, the primary principle is physicalistic, that is the assumption that the language of biology, chemistry, and physics is sufficient to explain disease, a complex biological phenomena which is restricted to what can be recognised and understood by the physician (Engel, 1977; Fava and Sonino, 2017). Thus, the biomedical model ignores the meanings of psychological, social and cultural terms in a patient report. In contrast to the biomedical model, Engel believes that illness is the result of the interaction of diverse causal factors, including those at molecular, organismic, individual, cultural, environmental, and social levels (Borrell-Carrió, Suchman and Epstein, 2004). He argues that biochemical defects alone do not account for all of an illness and that the biomedical model simplifies the risk factors, prevention, treatment, and control of illness (Engel, 1977). Furthermore, he argues that psychosocial factors, such as living conditions, constitute significant variables determining susceptibility, severity, and course of mental health problems and diabetes for example (Engel, 1977). In the 1980s and 1990s, a large body of

published research demonstrated a relationship between depression, stress, cardiovascular and cancer risk, and disease incidence (Stineman and Streim, 2010; Fava and Sonino, 2017). Thus, these findings challenged the assumptions of the traditional biomedical model of mind-body dualism, the doctrine that dissociate the somatic from the mental (Engel, 1977).

2.2.2 The biopsychosocial approach

To overcome the discussed limitations of the biomedical model, Engel called for the need of a new model for medicine in 1977, the biopsychosocial model (Engel, 1977). He wrote:

‘I contend that all medicine is in crises and further, that medicine’s crises derive from the same basic fault as psychiatry’s, namely, adherence to a model of disease no longer adequate for the scientific task and social responsibilities of either medicine or psychiatry’ (Engel, 1977, p. 129).

With the biopsychosocial model, Engel proposed to broaden the traditional biomedical approach, so that patients are still cared for from a disease and biological standpoint but, additionally, psychological and social factors would be equally considered in the care process (Farre and Rapley, 2017). Therefore, the biopsychosocial model presents a new medical model that combines the biomedical, psychological, and social dimensions of health. The statement of the World Health Organisation’s (WHO) Constitution that health is not merely the absence of disease or infirmity but a state of complete physical, psychological, and social wellbeing, expresses the underlying idea of the biopsychosocial model of health (World Health Organization, 2016). It applies a broad perspective on the determinants of health and shifts away from the view that biological indices are the ultimate criteria defining illness and poor wellbeing. Lastly, the biopsychosocial model does not follow the dualistic nature of the biomedical model, with its separation of body and mind, but instead assumes a mutual influence of mind and body on health and illness (Borrell-Carrió, Suchman and Epstein, 2004).

As a reaction to biomedical reductionism, the biopsychosocial approach to understanding health, illness, and healthcare delivery from the social, biological, and psychological perspective was widely accepted (Lindau *et al.*, 2003; Borrell-Carrió, Suchman and Epstein, 2004; Stineman and Streim, 2010; Hatala, 2012; Tanenbaum, 2015; Farre and Rapley, 2017). The WHO, for example, encouraged the use of the biopsychosocial model to consider health from a biological, but also individual and social perspective (Rosenbaum and Stewart, 2004). Furthermore, in the report ‘Improving general practice – a call to action’ NHS England stressed the importance to look at the patients’ physical, psychological, and social needs

together to understand a patient's biopsychosocial story (NHS England, 2013). Nevertheless, physical and mental healthcare in the UK today remains dominated by interventions that are within the sphere of medical expertise, hence the biomedical model (Busfield, 2010; Deacon, 2013). Scholars argue that a biomedical approach in medicine may be reinforced by the way medical and research institutions, medical encounters, and reimbursement systems are structured (Lindau *et al.*, 2003; Lane, 2014; Fava and Sonino, 2017).

In contrast to the quantitative focus in biomedical research, biopsychosocial research involves qualitative methods to collect and analyse information on psychological and social factors (Edozien, 2015). Although the introduction of the biopsychosocial model in the late 19th century responded to the narrow scope of the biomedical approach in clinical practice, RCTs to evaluate the clinical effectiveness of services remain the 'gold standard' till today (Tanenbaum, 2015). Authors suggested that dismissing non-randomised studies leads to a marginalisation of service types based on the biopsychosocial approach, which are not always amenable to quantitative experimental studies with pre-defined outcomes (Victora, Habicht and Bryce, 2004; Craig *et al.*, 2011). Consequently, this may introduce 'evaluative bias', whereby the evidence-base is dominated by health interventions amenable to quantitative experimental research and RCTs (Victora, Habicht and Bryce, 2004; Craig *et al.*, 2011). Besides the persisting dominance of RCTs in health research, the number of qualitative studies is increasing to understand the biopsychosocial approach to conditions and health service evaluations increasingly include a nested qualitative element (Souza *et al.*, 2011; Edozien, 2015).

Criticisms of the biopsychosocial model

There are a number of criticisms of the biopsychosocial model to be acknowledged.

1. The model is too vaguely defined and not testable

Authors have argued that the biopsychosocial model, as originally formulated by Engel, is limited by conceptual underdevelopment and the lack of operationalisation (Smith *et al.*, 2013b; Farre and Rapley, 2017). Consequently, predictions cannot be made and the biopsychosocial model cannot be empirically tested to evaluate it (Smith *et al.*, 2013b; Farre and Rapley, 2017).

2. The model is too general and cannot be efficiently put in practice

Another discussed limitation of the biopsychosocial model is that it is too generic in its scope, and therefore provides little guidance for policy makers and health professionals on how to implement and apply it in practice (Farre and Rapley, 2017). The model does not specify

what factors to prioritize and when (Freudenreich, Kontos and Querques, 2010). Without guidance, it can be overwhelming for health professionals to consider and collect data on biological, psychological, and social factors in clinical situations (Freudenreich, Kontos and Querques, 2010). Moreover, collecting loosely related biopsychosocial data from all patients is criticised for being too time consuming and inefficient (Farre and Rapley, 2017). In addition, the model does not specify the required resources for health professionals to respond and meet the identified non-medical needs of their patients.

3. No method is specified to identify and collect relevant biopsychosocial data

No methodological guidance is provided to assist the process of obtaining biopsychosocial data from individual patients (e.g. physical examinations, diagnostic tests, face-to-face interview with patients, talking with families) (Smith *et al.*, 2013b). To obtain biological information, a ‘doctor-led approach’ including physical examinations, diagnostic investigation, and a doctor led interaction by asking closed-ended questions in order to diagnose and treat disease may be most appropriate (Smith *et al.*, 2013b). On the other hand, to identify psychological and social information, a ‘patient-centred approach’ may be more appropriate, in which physicians follow the patient’s interests and concerns during the medical interview and ask open-ended and non-directive questions (Smith *et al.*, 2013b). However, the model does not include repeatable measures to consistently identify relevant biological, psychological, and social information in a consultation (Smith *et al.*, 2013b).

4. The model may reinforce mental health related stigma

The biopsychosocial model has been criticised for reinforcing the stigma associated with mental health (Tavakoli, 2009). Tavakoli (2009) argued that the distinction between psychology and biology in the model might indirectly reinforce the stigma that psychiatric diseases are volitional rather than medical issues.

Besides the criticisms of Engel’s biopsychosocial model, the idea of a biopsychosocial approach that would improve the traditional biomedical approach has become a reference-point in medical practice, education, and research (Smith *et al.*, 2013b; Farre and Rapley, 2017). Increasing numbers of people living with chronic conditions, multimorbidity, and frailty and increasing financial pressures on health systems also point to the inadequacies of the biomedical approach to manage and prevent illness (Richards, Coulter and Wicks, 2015). Focusing exclusively on biological factors, the diagnosis, and treatment of separate diseases appears to be more and more inadequate to deal with the complex population needs that require delivery systems that integrate a range of professionals and skills across sectors (Fava and Sonino, 2017). To respond to the challenges facing most health systems in developed

western countries, the broad principles of the biopsychosocial model have been increasingly included in guidance and policy documents (Goodwin *et al.*, 2012; Farre and Rapley, 2017).

2.3 The biopsychosocial approach in practice

2.3.1 Patient-centred care

Patient-centred care is necessary to implement the biopsychosocial approach in health care (Smith, 2002; Smith *et al.*, 2013b; The Health Foundation, 2016; Farre and Rapley, 2017; Allen, Scarinci and Hickson, 2018). There is no single, universally agreed definition of the term ‘person-centred care’ and it is still an emerging and evolving area in health care. However, taking the patients’ needs, values, preferences, and priorities into account, and aiming to understand patients’ biopsychosocial story rather than applying a narrow focus on their condition or symptoms of individual diseases are core principles of patient-centred care (Smith, 2002; Kaba and Sooriakumaran, 2007; Greene, Tuzzio and Cherkin, 2012). Other core principles include improved patient involvement in decision-making, more equal and strong relationships between patients and clinicians, empowering people to take control over their own health through self-care, life-style, and behaviour changes, and supporting people to live an independent and fulfilling life (Kaba and Sooriakumaran, 2007; Richards, Coulter and Wicks, 2015). However, in order to respond to the identified biopsychosocial and personal needs of patients, the provision of comprehensive and continuous care within and across sectors, i.e. integrated care, is necessary.

2.3.2 Integrated care

In many high income countries, care is provided in a disconnected and fragmented way with a lack of coordination across care providers and settings (Araujo de Carvalho *et al.*, 2017). Such fragmentation can result in suboptimal care and clinical outcomes, poor patient experiences, and higher costs for patients and health care systems due to the duplication of work (Araujo de Carvalho *et al.*, 2017; Baxter *et al.*, 2018). Integrated care has been discussed all over the world and is attracting attention as an important approach to develop more cost-effective, coordinated, and continuous care to tackle multimorbidity, frailty, and the complex needs of populations in the context of growing financial pressures (Kodner, 2009; Sun *et al.*, 2014; Araujo de Carvalho *et al.*, 2017). Increasingly, integrated care is perceived as essential to sustaining health systems (Araujo de Carvalho *et al.*, 2017; Baxter *et al.*, 2018). However, there is no universally agreed meaning and definition of the term ‘integrated care’ and within the literature, integrated care is also called ‘managed care’, ‘coordinated care’, ‘continuity of care’, ‘comprehensive care’, ‘collaborative care’, and ‘transmural care’ (Armitage *et al.*, 2009; Kodner, 2009). In addition, previous studies have found that the term ‘integrated care’ is often used as an umbrella term including initiatives

based on different types of integration, settings, scopes, and values (Armitage *et al.*, 2009; Kodner, 2009; Stein and Rieder, 2009; Nurjono *et al.*, 2016; Leijten *et al.*, 2018). The diversity of definitions and meanings has been driven by the different perspectives of stakeholders and purposes they attribute to the term (Kodner, 2009; Goodwin, 2016). However, the principle characteristics of integrated care are to bring together (i.e. to integrate) fragmented aspects of a care system to improve the quality and safety of care services through on-going and co-productive partnerships (Goodwin, 2016). For the purpose of this study, integrated care is defined as an approach that seeks to improve the quality of care for individual patients, service users, and carers by ensuring that services are attuned to their needs and preferences and well-coordinated across multiple professionals, organisations, and sectors (Leutz, 1999; Goodwin *et al.*, 2012; Valentijn, Ruwaard, *et al.*, 2015; Goodwin, 2016). In addition to the lack of specificity and clarity inherent in the definition of integrated care, there is a conceptual inconsistency as concepts and theories from different scientific fields were frequently applied to conceptualise integrated care (Kodner and Spreeuwenberg, 2002; Stein and Rieder, 2009; Valentijn *et al.*, 2013). Moreover, Valentijn *et al.* (2013) suggests that existing theories and concepts applied to underpin integrated care in the literature are based on top-down control strategies of change (e.g. the linear structure-process-outcome framework and industrial-quality improvement logic) and therefore tend to overlook the multifaceted nature and non-linear, complex dynamics of the integration process. Furthermore, the conceptual inconsistency and non-existence of a common terminology and definition of integrated care makes it difficult to compare research findings and experiences across studies (Stein and Rieder, 2009; Valentijn *et al.*, 2013; Baxter *et al.*, 2018). It also hampers systematic understanding and thus makes it difficult for policy-makers, commissioners, managers, clinicians, and researchers to develop, implement, maintain, and evaluate integrated care efforts in practice (Kodner, 2009; Stein and Rieder, 2009; Valentijn *et al.*, 2013; Baxter *et al.*, 2018). Increasingly, scholars have called for the establishment of a common terminology and the development of conceptual frameworks acknowledging the multifaceted and complex nature of integrated care (Kodner, 2009; Stein and Rieder, 2009). To promote better and shared understanding of the complex phenomenon of integrated care from a primary care perspective, Valentijn *et al.* (2013) developed a conceptual framework, called 'Rainbow Model of Integrated care' (RMIC). This conceptual framework provides the theoretical underpinning of this study and is discussed in detail in Chapter 4 of this thesis.

There is a need to distinguish between two common forms of integration: Vertical and horizontal integration (Valentijn *et al.*, 2013; Baxter *et al.*, 2018). Vertical integration focuses on the integration between different (vertical) levels within the health system, for example, the integration of primary care services with secondary and tertiary care services (Valentijn *et*

al., 2013; Baxter *et al.*, 2018). Vertical integration is based on a disease-focused view, as it is related to the idea that diseases are treated at different levels of specialisation across health sectors (Valentijn *et al.*, 2013). Horizontal integration is related to the integration of health services, social services, and other care providers and is usually based on the development of multi-disciplinary teams or networks (Goodwin, 2016). In contrary to vertical integration, horizontal integration is based on the holistic-focused view, as it aims to improve the overall health of people through collaboration across different sectors and professional groups (Valentijn *et al.*, 2013). To counteract the existing fragmentation in care delivery and improve continuous and coordinated care across the entire care continuum, both vertical and horizontal integration are needed. However, the distinction between these integration forms is important, because they are based on different conceptual frameworks and require different techniques and resources to be achieved (Valentijn *et al.*, 2013). This study focuses on the integration between primary health care and social services, i.e. horizontal integration, in the NHS.

Thus, both a patient-centred approach and horizontally integrated care are necessary to meet the medical and non-medical needs of patients determining their health and wellbeing. A patient-centred approach is important to direct clinical attention to social, psychological, and behavioural dimensions of illness, rather than to biological factors only (Farre and Rapley, 2017). However, to address the wider determinants of health and wellbeing (e.g. stress, concerns about life changes, incapacity to work, housing issues, social isolation, and poor lifestyle), horizontally integrated services are necessary to provide continuous care and meet the identified non-medical needs. Despite the increasing policy attention on integrated care, the links between primary health care services and the voluntary and community sector are often underdeveloped in the UK (Charles *et al.*, 2018). Funding pressures on the NHS, cuts in public spending on social care and public health, the increasing demand for health and social care, problems arising from relationships across different professional cultures and organisations, and short-term funding, make it difficult to integrate health and social care services sustainably in real life (Popay *et al.*, 2007b; Charles *et al.*, 2018). However, in the absence of integrated services and appropriate onward referral options, GPs tend to respond to psychosocial problems with consolation and reassurance, or treat the consequences of psychosocial problems with medical interventions, rather than responding to the psychosocial problems themselves (Wilson and Read, 2001; Popay *et al.*, 2007a; Brandling and House, 2009). Previous research highlights that many GPs in the NHS prescribe antidepressants due to a lack of alternatives, despite believing that other approaches may be more effective to respond to the patients' mental health needs (Popay *et al.*, 2007a; Maughan *et al.*, 2016). Given the limited time of consultations and available resources, responding to complex psychosocial problems can be a frustrating experience for healthcare professionals in the NHS

(Popay *et al.*, 2007a; Brandling and House, 2009; Mossabir *et al.*, 2015). Previous studies found that GPs rarely refer patients to local community groups or advice services directly, due to a lack of up-to-date knowledge of local resources (Popay *et al.*, 2007b; Mossabir *et al.*, 2015).

One possible approach to bridge the gap between the psychosocial needs of patients and the ability of traditional health services to meet these demands would be to work in partnership with the voluntary and community sector (i.e. horizontal integration), where many relevant services, such as exercise classes, support groups, social activities, and advice services are provided (Mossabir *et al.*, 2015). To counteract the fragmentation between social and primary health care services, SP initiatives have been increasingly implemented across the UK in recent years (Dayson, 2017). The overreaching aims of SP are (Bertotti *et al.*, 2017; Carnes *et al.*, 2017; Dayson, 2017):

- To improve personal well-being and the wider determinants of health such as isolation, self-esteem, and health behaviours
- To help people to manage their (chronic) conditions and take control over their own health
- Prevent the development of health problems (primary prevention) and their worsening and recurrence (secondary prevention)
- Reduce demand on primary and secondary health services

SP initiatives in the UK are the focus of this study and will be discussed in more detail in the following sections.

2.4 Social prescribing

2.4.1 Policy context for social prescribing in the UK

Government initiatives, guidelines, and key policy reports including the Marmot Review, the NHS Five Year Forward View, Sustainability Transformation plans (STPs), the General Practice Forward View, the National Institute for Health and Clinical Excellence (NICE) guidelines, the inception of the Improving Access to Psychological Therapy (IAPT) program, setting up Clinical Commissioning Groups (CCGs), and the high-level national outcomes of the NHS have provided a supportive climate for funding, development, and implementation of SP initiatives in the UK.

The Marmot review, published in 2010, is an independent review to propose strategies for reducing health inequalities in England (Marmot *et al.*, 2010). Findings of the Marmot Review have guided national and international health policy, has shaped public health services, raised awareness about social determinants of health, and increased commitment from health professionals and service providers to address them (University College London, 2014). One key message of the Marmot Review is that actions across the social determinants of health, which are beyond the reach of health services provided in the NHS, are required to reduce health inequalities and improve the health and wellbeing of all people (Marmot *et al.*, 2010). The Review highlights the importance of the wider determinants of health, such as housing issues, low self-esteem, and isolation, in relation to health and wellbeing and supports the shift towards the biopsychosocial approach, patient-centred care, and integration of health and social care services. Similar to SP, creating conditions for people to take control over their own health and ill-health prevention, is key to Marmot's approach (Marmot *et al.*, 2010). Overall, the concept and previously discussed aims of SP are reflected in the policy objectives based around the social determinants of health, suggested by Marmot (Marmot *et al.*, 2010):

1. Giving every child the best start in life
2. Enabling all children, young people and adults to maximize their capabilities and have control over their lives
3. Creating fair employment and good work for all
4. Ensuring a healthy standard of living for all
5. Creating and developing sustainable places and communities
6. Strengthening the role and impact of ill-health prevention

Therefore, this influential report supports the underlying concept of SP and creates a supportive climate for SP initiatives in the UK. Whereas SP was not specifically mentioned in the Marmot Review, its routine implementation across London is an objective of London's current health inequalities strategy (Greater London Authority, 2017). Including SP in such strategies, further promotes its implementation across the UK.

The Five Year Forward View and General Practice Forward View are two health policy documents regarded as supportive of the approaches and concept inherent to SP (Husk *et al.*, 2016; Bertotti *et al.*, 2017; Bickerdike *et al.*, 2017; Woodall *et al.*, 2018). The NHS's Five Year Forward View sets out a view on how the NHS needs to evolve over the next five years and beyond to meet the changes in patients' health needs, marked by multimorbidity and chronic conditions (NHS England, 2014). Dissolving the traditional divide between primary

care and community services and the development of stronger partnerships with charitable, community, and voluntary sector organisations are outlined as key steps to provide personalised and coordinated services in the future (NHS England, 2014). In addition, patient empowerment, supporting people to manage and control their own health, health promotion, and primary and secondary prevention were identified to be integral to the sustainability and long-term future of the NHS (NHS England, 2014). The Sustainability and transformation plans (STPs), are five-year local delivery plans for the Forward View in England (Charles *et al.*, 2018). Given that SP has the potential to promote the required transformation of service delivery as outlined in the Forward View, SP initiatives are included in many STPs across England (Barnacle and Crowe, 2017). Moreover, the NHS's report on the 'Next steps on the NHS Five Year Forward View', includes plans on working with primary care and the third sector to design a common approach to make self-care and SP systematic and equitable across England (NHS, 2017). SP was also highlighted in the General Practice Forward View as an initiative to support the integration of primary care with wider health and care services to release capacity in GP surgeries (NHS England, 2016). Including SP in the current transformation of the NHS and in the development of new care models provides a supportive policy context for the funding, design, and implementation of SP.

The National Institute for Health and Care Excellence (NICE) guideline's on the management of anxiety and depression include cost-effective approaches that potentially fall under the SP umbrella, for example exercise-referral, self-help, bibliotherapy, and social support (National Institute for Health and Clinical Excellence, 2004, 2011). Thus, although the NICE guidelines do not refer directly to SP, they provide some evidence on the effectiveness and cost-effectiveness of activities and interventions that are provided by community and voluntary sector organisations as part of SP. In line with the NICE guideline 2004 to reduce the prescription of antidepressant drugs for mild to moderate depression, the Improving Access to Psychological Therapies (IAPT) programme was set up in 2011 in the UK (Thomson, Camic and Chatterjee, 2015). The IAPT program aims to ensure equal access to talking therapies for people with common mental health problems such as depression or anxiety disorders (Department of Health, 2011). It is an example for a shift away from medication towards alternative pathways to respond to depression in primary care. Thus, in line with the concept of SP, it expands the range of service options in primary care, offers greater service user choice, and patient-centred care to improve health and wellbeing (Keenaghan, Sweeney and McGowan, 2012).

Following the Health and Social Care Act in 2012, Clinical Commissioning Groups (CCGs) replaced Primary Care Trusts in April 2013 (NHS England, 2015). CCGs are clinically-led

statutory NHS bodies, responsible for the planning and commissioning of health care services for their local area, such as mental health services, emergency care, and community care (NHS England, 2015). They are independent and accountable to the Secretary of State for Health. As local authorities are responsible for public health, CCGs work closely with them through health and wellbeing boards, by developing a joint needs assessment and strategy for improving public health (NHS England, 2015). CCGs aim to determine priorities and commissioning healthcare to obtain the best possible outcome for their local community. Therefore, CCGs are instrumental in commissioning SP and were identified as a major funding source for local SP programmes in the UK (Polley *et al.*, 2016; Bertotti *et al.*, 2017).

In addition to the relevance at a local level, the overreaching aims of SP also link directly to the high-level national outcomes of the NHS, such as preventing premature mortality and improving the quality of life for people with LTCs. These outcomes are outlined in the NHS Outcome Framework (Figure 1), which consists of 68 indicators, which are grouped in five domains, to measure performance of the NHS at a national level (Department of Health, 2014).

Domain 1	Preventing people from dying prematurely;
Domain 2	Enhancing quality of life for people with long-term conditions;
Domain 3	Helping people to recover from episodes of ill health or following injury;
Domain 4	Ensuring that people have a positive experience of care; and
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm.

Figure 1: The NHS Outcome Framework 2015/16 (Department of Health, 2014)

SP, therefore, is aligned to national and local policy priorities and the planned transformation of the NHS towards better integration between primary care and third sector organisations.

2.4.2 Social prescribing delivery models in the UK

As mentioned in the introduction chapter of this thesis, there is no agreed definition of SP (Husk *et al.*, 2016; Carnes *et al.*, 2017). Previous research showed that a range of different SP models have emerged in the last 10 years in the UK, as the aims of SP schemes and their respective delivery models can have major variance (Husk *et al.*, 2016). SP schemes can vary, for example, in their referral routes (individuals can self-refer, or health professionals, social care, and other relevant professionals can make a referral to SP) and the level of support provided by navigators to service users (Bertotti *et al.*, 2017; Woodall *et al.*, 2018). In order

to differentiate between approaches to SP, Kimberlee (2015) developed a widely used typology, arranging SP models into (i) signposting, (ii) light, (iii) medium, and (iv) holistic. The features of each of the four models proposed by Kimberlee (2015) will be discussed in the following section.

Social prescribing signposting

In this model, GPs can signpost patients to the SP programme and leave them to their own to access and follow through available local networks and groups who may help individuals to address their non-medical needs (Kimberlee, 2015). Alternatively, the SP programme may simply share the space of the practice and seek to address patients non-medical needs without any regular or formal links with GPs (Kimberlee, 2015). If the practice has no strong direct relationship with the SP programme there will be little or no feedback and communication between surgeries and SP programmes.

A local example of a SP signposting model is a SP programme called ‘Social Mirror’ in Knowle West, UK. This model is based on a tablet application that allows individuals to measure, visualise, and see the potential for change by providing them online and offline access to networks of wellbeing support (Kimberlee, 2013). Another example is the ‘Well Aware’ programme, which provides a free online guide to a large number of health, wellbeing, and community initiatives in Bristol, South Gloucestershire, Bath and North East Somerset, North Somerset and Somerset (Kimberlee, 2013).

Social prescribing light

SP light models are community or primary-care based interventions in which relevant professionals refer vulnerable or at risk individuals to specific programmes to help them meet their non-medical needs or achieve their goals (Kimberlee, 2013). Examples for such local programmes are exercise on prescription, arts on prescription, or prescriptions for learning (Friedli, Vincent and Woodhouse, 2007; Kimberlee, 2015).

Social prescribing medium

This SP model is based in general practice surgeries and involves navigators (Kimberlee, 2015). The SP medium model is based on partnership work with GPs and aims to address certain needs and behaviours identified by GPs (Kimberlee, 2015). The navigator sees referred patients and provides advice on, for example, exercise, diet, and nutrition. In addition, navigators in this model promote self-care and signpost to voluntary organisations or self-help groups for specific disease areas (e.g. patients with heart disease or diabetes) or non-medical needs (social isolation, physical activities) (Kimberlee, 2015).

Social prescribing holistic

In this model, SP is based in the general practice surgery and involves navigators. Holistic models require partnership working between SP, GP surgeries, and third sector organisations. Moreover, in this model, primary care services and SP operate with their own but connected governance arrangements. Formal referral pathways (e.g. letter, form, online referral, or telephone call) is used by GPs to refer patients into SP. Health professionals accept SP to offer potential solutions to psychosocial issues that they cannot address in normal appointment time. In essence, the navigator has the role to identify, together with the service user, the non-medical problems (adopting a holistic perspective) that triggered a health or wellbeing issue. A patient may be referred to SP to improve diet, but in the holistic model the navigator will explore all patient needs and wider determinants of health and wellbeing. Navigators provide practical, emotional, and social support to service users while being enrolled on the programme. Service users are encouraged to play a central role in managing and controlling their own health. Although time parameters may be set, the number of sessions offered to service users is dependent on the patient's needs explored in the holistic approach. Holistic models usually have a wide range of activities and services in the local third sector available for service users. Examples of sources of support, predominantly provided by local services, include art therapy, walking and reading groups, exercise classes, nature-based activities, creative activities, volunteering, legal advice, and support with employment, debt, and housing (Moffatt *et al.*, 2017). Holistic SP models evolve flexibly over time and sometimes from SP programmes previously described as signposting, light, or medium. Most of the recent SP approaches in the UK can be described as 'holistic' (Kimberlee, 2015).

The Luton SP programme, which will be assessed in more detail in this thesis, is most similar to the 'holistic SP model', as it includes a clear referral pathway from the GP to the programme, a holistic view of patient's needs and aspirations, and an intense level of support provided by navigators depending on service users' needs. However, it is important to note that there may be differences between the pathways (e.g. referral routes, number and length of sessions with navigators), geographic coverage, funding and investment, and aims of 'holistic' SP models in the UK (Bertotti *et al.*, 2017; Dayson, 2017; Rempel *et al.*, 2017; Woodall *et al.*, 2018). Therefore, it is important that researchers transparently describe SP models and the implementation context, so that research findings and experiences can be understood in context and compared.

2.4.3 Potential challenges to the implementation and maintenance of social prescribing

From the literature, several potential challenges for SP programmes can be identified. Firstly, the biomedical model dominates primary health care services. Secondly, the fundamental differences between primary care and third sector organisations can make partnership working across sectors difficult. Thirdly, most SP programmes are based on short-term funding and there is a lack of finances for third sector resources. Lastly, there is a lack of rigorous evidence for SP programmes. These potential challenges will be discussed in more detail in the following sections.

The dominance of biomedicine

As discussed earlier in this chapter, the biomedical model remains dominant in primary care practice (Edmonds, 2003; Brandling and House, 2007; Busfield, 2010). Thus, routine practice in primary care is biased towards the traditional biomedical model. It may be challenging to encourage primary care staff to step outside biomedical model thinking and integrate a biopsychosocial approach into primary care practice (Edmonds, 2003). To open up a discussion with the patient about the possibilities of SP, instead of medical interventions, health professionals may also need to change their consultation style (Friedli, Themessl-huber and Butchart, 2012). In addition to required changes in behaviours and perspectives on the provider side, the acceptance of patients that a clinical pathway is not the only option is crucial for the implementation of SP too (Chaudoir, Dugan and Barr, 2013; Whitelaw *et al.*, 2017). Previous research by Brandling and House (2007) on the feasibility of SP services in primary care found that patients consider health professionals as the most appropriate source for treatment, advice, and cure, which may be a reflection of the societies' entrenchment in the traditional biomedical approach to healthcare. The patient expectation of immediate outcomes (i.e. a quick fix) and taking a passive role in treatment may challenge the long-term, preventative approach of SP which encourages patients to take an active role and control over their own health (Brandling and House, 2009).

Differences between health and social organisations

There are fundamental differences in culture, language, habits, and behaviours between healthcare and community and voluntary sector organisations, tracing back to their histories (Friedli, Vincent and Woodhouse, 2007). While these differences between health and social care organisations can promote creativity and enhance problem solving, it can also be a source of communication and coordination difficulties (Ferlie *et al.*, 2005). Potential barriers to integration and partnership working are, for example, limited awareness and understanding of the responsibilities, activities, and roles of agents across social and healthcare organisations

(RAND Europe, 2012; Tsasis, Evans and Owen, 2012). Furthermore, hierarchical structures and the unequal distribution of power within partnerships can inhibit partnership working between different sectors (Carr *et al.*, 2006). Medicine is a long-established professional organisation whose members are regarded as ‘professional elite’, predominantly drawn from a well-educated upper class (Irvine *et al.*, 2002). In the 20th century, healthcare delivery was based around the medical practitioner alone, who had all the decision-making power and authority (Irvine *et al.*, 2002). In contrast, social work is a relatively new field, whose members are predominantly women and are drawn from a variety of social classes and educational backgrounds (Irvine *et al.*, 2002). Although the biopsychosocial approach increasingly challenges the dominance and autonomy of medicine, the power of medicine combined with the high degree of professional self-confidence and the traditional practice of directing and coordinating the work of other occupations, is likely to create a barrier to partnership working between primary care and third sector organisations (Irvine *et al.*, 2002; Carr *et al.*, 2006). Therefore, apparent points of contradiction and differences in organisational histories need to be taken into account when organisations seek to partner to deliver integrated care (Tsasis, Evans and Owen, 2012). Time and resources need to be dedicated to support inter-professional groups and organisations to exchange information and learn from each other to understand the distinct professional cultures, languages, and ideologies (Tsasis, Evans and Owen, 2012). Hence, interaction between professionals across sectors and relationship building are crucial to counteract historical social dynamics that may hinder integration and, hence, the implementation and maintenance of SP schemes (Chandler *et al.*, 2016).

Short-term funding and lack of finances for third sector resources

Funding pressure on the NHS, local authority, and central government and cuts in funding for the community and voluntary sector create a challenge for the implementation and sustainability of SP services, particularly for the holistic SP model (Whitelaw *et al.*, 2017; Charles *et al.*, 2018). When funding is tight, the support, attention, and funding shifts further away from third sector organisations and public health (NHS England, 2014; Charles *et al.*, 2018). Well established third sector resources, however, are a key component of SP models and necessary for the successful implementation and sustainability of SP schemes (Friedli, Themessl-huber and Butchart, 2012; Farenden *et al.*, 2015). In the past, funding cuts for third sector organisations led to longer waiting lists and reductions in scope and client criteria, making it more challenging for navigators to refer service users onward to services provided by third sector organisations (Farenden *et al.*, 2015). Previous studies also found that some third sector organisations are not able to meet the additional demand on their services due to SP without additional financial resources (Whitelaw *et al.*, 2017; Skivington *et al.*, 2018).

Lastly, short-term funding streams for SP schemes, and therefore for third sector organisations to provide services, were identified as a major barrier to the sustainability of SP services and inter organisational partnerships (The Health Foundation, 2015; Whitelaw *et al.*, 2017).

Existing evidence base for social prescribing

A review of SP programs in the UK highlighted that nearly 60% of reviewed SP programs were not evaluated (Thomson, Camic and Chatterjee, 2015). In addition to a general scarcity of evaluations and published empirical studies, the rigour and quality of most existing evaluations of SP services were limited (Bickerdike *et al.*, 2017; Pilkington, Loeff and Polley, 2017). Common methodological shortcomings of evaluations include poor reporting of sampling, data collection, and analysis methods, as well as short follow-up durations, missing data, no consideration of potential confounding factors, and a lack of validated measurement tools and comparative controls (Bickerdike *et al.*, 2017). Although SP schemes were increasingly implemented across the UK, there is limited evidence on factors affecting the implementation of local SP services, patient uptake, and adherence. This ‘evidence gap’ prevented information sharing and policy-makers, managers, and providers to learn from previous experiences. Most studies on SP focused on outcome evaluations. Some of the service evaluations indicated beneficial changes in anxiety, depression, wellbeing, levels of positive and active engagement in life, and social isolation for service users, whereas others have not (Dayson and Bashir, 2014; Bickerdike *et al.*, 2017; Carnes *et al.*, 2017; Woodall *et al.*, 2018). Therefore, the evidence base for the impact of SP on service users is mixed and limited by methodological shortcomings. Although it has been suggested in the General Practice Forward View that SP has the potential to decrease the demand on primary care, there is mixed evidence about whether SP services reduce the financial costs of healthcare and primary healthcare resource use (Maughan *et al.*, 2016; Bickerdike *et al.*, 2017). Commentators have increasingly questioned whether the momentum and enthusiasm for SP is warranted based on the existent evidence base (Bickerdike *et al.*, 2017; Carnes *et al.*, 2017; Woodall *et al.*, 2018). However, the mixed outcomes make commissioning decisions on the implementation and continuation of SP schemes challenging (Bickerdike *et al.*, 2017). To strengthen the existent evidence base on SP, clear and transparent reporting of research studies is required, as well as longer-term quantitative studies with larger sample sizes and comparative control groups (Maughan *et al.*, 2016; Bickerdike *et al.*, 2017; Carnes *et al.*, 2017). This study aims to address the identified knowledge gaps and contribute to the strengthening of the existent evidence base on holistic SP models in the UK.

2.5 Chapter summary

This chapter has provided an overview of the different theories and approaches that have influenced healthcare and research since the end of the 19th century up to today. In particular, the biomedical and biopsychosocial model of healthcare were discussed and compared in this chapter. The relevance of the biopsychosocial model was examined in the context of the wider determinants of health, increasing prevalence of chronicity and multimorbidity, and financial pressures on the NHS. In addition, the components (patient-centred and integrated care) required to implement interventions based on the biopsychosocial approach in real life were explored in this chapter. An example of a real life intervention based on the biopsychosocial approach is SP. The UK policy context for SP, different SP delivery models in the UK, and potential challenges to the implementation and maintenance of SP schemes were discussed in this chapter. The Luton SP programme provides a local example that will be assessed in more detail in this research study. The pathway of the Luton SP programme and the local implementation context is discussed in detail next (Chapter 3).

3 Chapter 3: The Luton social prescribing programme

3.1 Introduction

The SP scheme in Luton is a local example of a SP programme and provides the basis for the primary qualitative and quantitative research of this work. This chapter begins with an overview of Luton's demographics and then moves the attention to the Luton SP programme.

3.2 Demography of Luton

Luton is a town in the East of England, located about 30 miles northwest of London, and has approximately 214,700 residents (Luton Borough Council, 2018). Figure 2 shows the map of Luton. Based on the Index of Multiple Deprivation (IMD) Luton is currently ranked 58th most deprived area in England out of 326 local authorities (Department for Communities and Local Government, 2015). It belongs to the top ten per cent most deprived areas in England (Research and Geospatial Information Team, 2015). In addition, Luton is an ethnically diverse and multicultural urban town with about 55% of Luton's population from Black and Minority Ethnic (BME) groups (Luton Borough Council, 2015a). The health of people living in Luton is generally worse than the national average (Public Health England, 2018).



Figure 2: Map of Luton (Public Health England, 2018)

3.2.1 Health and life expectancy inequalities in Luton

Health inequalities manifest themselves in many ways based, for example, upon gender, ethnicity, age, and social class. Studies on BME communities showed that individuals from minority ethnic groups often view themselves as stigmatised and disadvantaged groups (Leamy *et al.*, 2011). Indeed, evidence showed that BME households are larger but their

homes smaller, and more likely to be in poor conditions compared to the national average (Garrett, Piddington and Nicol, 2014). Furthermore, it is acknowledged that BME populations often experience barriers to accessing health services and poorer health (Szczepura, 2005). It was estimated, for example, that BME communities in Luton are six times more likely to develop type 2 diabetes mellitus (T2DM) than the white European communities in Luton (Luton Borough Council and NHS, 2012). Thus, in addition to health inequalities in Luton compared to the national average, there are also health inequalities within Luton. In addition to existing health inequalities, inequalities in life expectancy exist within Luton and widened over the past years (Luton Borough Council, 2015c). The life expectancy of men and women living in the most deprived areas of Luton is on average 10.4 years and 6.3 years lower, respectively, compared to those living in the least deprived areas (Public Health England, 2018). The Luton SP model was partly implemented to help reduce health inequalities in Luton (Luton Borough Council, 2015b and Business case, 2015 not published). Implementing SP in primary care provides healthcare professionals with a referral option to respond to the social causes of health inequalities at the individual level. Many of the social causes, for example isolation, poor nutrition, housing issues, and low or no income, are likely to be inter-generational and to affect children from an early age (Popay *et al.*, 2007b). Hence, through addressing the wider social determinants of health and helping people to access appropriate non-clinical support, such as advice, guidance, and healthy lifestyle services, SP may help to reduce existing health inequalities across generations (Luton Borough Council, 2015c).

3.2.2 Health and wellbeing trends in Luton

As outlined in Chapter 1 and Chapter 2 of this thesis, the increasing prevalence of chronic conditions, such as T2DM and COPD, provides a challenge at a national and international level. Apart from physical ill health and complex medical needs, LTCs are often associated with increased psychosocial needs, impacting on peoples' mental and physical health and wellbeing, social functioning, and self-care (Marmot *et al.*, 2010; Morris *et al.*, 2011; Maughan *et al.*, 2016). It is estimated that if the current trends in population change and obesity persist, the total prevalence of diabetes in Luton is expected to rise to 9% by 2020 and 10.3% by 2030 (Luton Borough Council, 2015a). T2DM is associated with retinopathy, neuropathy, kidney failure and heart disease (Bolge, Flores and Phan, 2016). The risk of developing T2DM can be reduced by lifestyle choices including increased physical activity, a healthy diet, and normal weight. COPD is the second highest cause for Accident and Emergency (A&E) attendance in England. In Luton, COPD related hospital admissions were higher than the England average in 2013/2014 (Luton Public Health Intelligence Team, 2016). High rates of A&E admissions are associated with poorer disease management of COPD and therefore highlight the need for improvement in self-care (Luton Public Health

Intelligence Team, 2016). Chronic conditions such as T2DM and COPD are commonly intertwined with poor mental health and wellbeing. The co-existence of a mental disorder, such as depression or anxiety, in co-morbidity is a major determinant of disability, impaired quality of life, poor self-care, lower adherence to treatment, and poorer clinical outcomes in many chronic diseases (Oladeji and Gureje, 2013; Bolge, Flores and Phan, 2016; Carta *et al.*, 2017). The prevalence (12.3%) of mixed anxiety and depressive disorder in Luton is higher than the national average (8.9%) (Luton Borough Council, 2015a). Previous research consistently found that mental health is influenced by the social determinants of health (e.g. living conditions, social isolation) (Marmot *et al.*, 2010). In addition, there is evidence for a bidirectional relationship between lifestyle factors and physical as well as mental health (Velten *et al.*, 2014). Relatively small changes in lifestyle choices, including engagement in physical activity, participating in cultural, creative, and mental activities like singing in a choir, reading a book, and eating a healthy diet was associated with important improvements in health and wellbeing in previous studies (Hannah, Lindsay and Kristel, 2014; Velten *et al.*, 2014). Implementing SP in Luton may help to build an infrastructure that connects primary care patients with the sources of support they need to embrace healthier lifestyle choices, improve self-care and disease management, and engage patients in activities that promote health, wellbeing, and social inclusion.

3.2.3 Informal carers in Luton

Informal carers are often family members and friends and have been defined as someone who spends a proportion of their time providing unpaid support to a family member, partner or friend who is ill, frail, disabled or has mental health or substance misuse problems (Greenwood, Mezey and Smith, 2018). The estimated proportion of carers (9%) within Luton was lower than the national average (10.2%), which might be expected given the comparatively younger population in Luton (Luton Borough Council, 2015a). In line with a renewed statutory focus on the needs of carers introduced by the Social Care Act in 2014, the Luton Carers Strategy sets out the Luton Borough Council's, Luton CCG's and the University of Bedfordshire's plans to meet the needs of the town's carers (Luton Borough Council, 2014). Previous research found that carers often feel stigmatised, socially isolated, have financial difficulties, and face restrictions in leisure participation as a result of caring for someone (Greenwood, Mezey and Smith, 2018). Parallel to the estimated increases in the prevalence of chronic conditions, it is likely that the proportion of carers in Luton is increasing too. SP in Luton may help support identified carers to access community based support systems in recognition of their needs, rights, and vulnerabilities from a health and wellbeing perspective, and is therefore aligned with local priorities and strategies.

3.3 The Luton social prescribing model

The Luton SP programme received funding for a three-year period (2015-2018). It was funded through the NHS Better Care Fund and implemented across four general practices in Luton. The NHS Better Care Fund is a programme across the NHS and local government that seeks to integrate health and social care services to promote patient empowerment, self-care, health and wellbeing, and independent living in communities. The Luton SP programme was based on previously existing relationships between healthcare and third sector organisations. In partnership with most general practices in Luton and the Luton and Dunstable University Hospital, the community organisation 'Active Luton' provided different physical activity services to patients, including exercise sessions for specific conditions such as COPD, stroke, or cancer and aerobics classes. The community organisation 'Live Well Luton' provided a number of healthy lifestyle interventions and behaviour change programmes to primary care patients, including stop smoking and weight management services. The community organisations Active Luton and Live Well Luton were key partners in the Luton SP programme and also involved in the development and implementation of the pilot programme.

3.3.1 Aims of the Luton social prescribing programme

The aims of the Luton SP programme were as follows (Luton Borough Council, 2015b):

- To reduce health inequalities within Luton
- To promote good health and independence for adults and older people with LTCs and carers
- To empower individuals and communities to have greater control over their own health
- To strengthen community development
- To develop and improve the integration of health and social care services

3.3.2 Eligibility criteria

Based on the needs of the local community, the key target groups of the Luton SP programme included (Luton Borough Council, 2015b):

- People with high risk for- or diagnosis with- T2DM and COPD
- People with mild to moderate mental health issues, particularly depression and anxiety
- People who are experiencing loneliness and/or social isolation

- Carers

Although the specific focus was on the patient groups outlined above, GPs had the option to refer all patients who could benefit from SP to the programme. To do so, the category ‘Other’ was included on the referral form to SP.

3.3.3 The Luton social prescribing pathway

In the Luton SP programme, participating GPs identified primary care patients who could benefit from SP and processed a referral to the programme. A formal referral form was used. Following the referral, navigators contacted the patients to arrange an initial appointment held in the surgery. The role of navigators involved:

- Assessment and discussions to identify the non-medical needs of service users, ensuring service user involvement in decision-making
- Motivational interviewing
- Processing onward referrals to sources of support usually provided by third sector organisations
- Supporting uptake and adherence of referred services and, if needed, accompany service users to referred services
- Providing on-going support based on the service users’ needs
- Data collection
- Keeping up-to-date with local services, developments, and changes in the community
- Relationship development and maintenance with third sector organisations to facilitate partnership working with local groups, networks, and organisations

The Luton SP programme offered a comprehensive and diverse range of services to service users, including art therapy, special interest clubs, walking and reading groups, exercise and yoga classes, nature-based activities, legal advice, and support with employment, debt, and housing. Local community organisations and groups had to complete an accreditation process to be part of the SP programme and to be able to receive referrals from navigators. The number of sessions with the navigators was not restricted and dependent on the service user’s needs. The exit point of service users could vary based on circumstances and the individual but usually navigators referred service users to twelve sessions provided by third sector organisations. These sessions were free of charge for service users while being enrolled in the SP programme. Service users could continue with the services after the SP programme but were required to cover the costs themselves. Figure 3 summarises the pathway of the Luton

SP model. In light of the classification of SP programmes by Kimberlee (2014) discussed in Chapter 2 of this thesis, the Luton SP programme is classified as ‘SP holistic’.

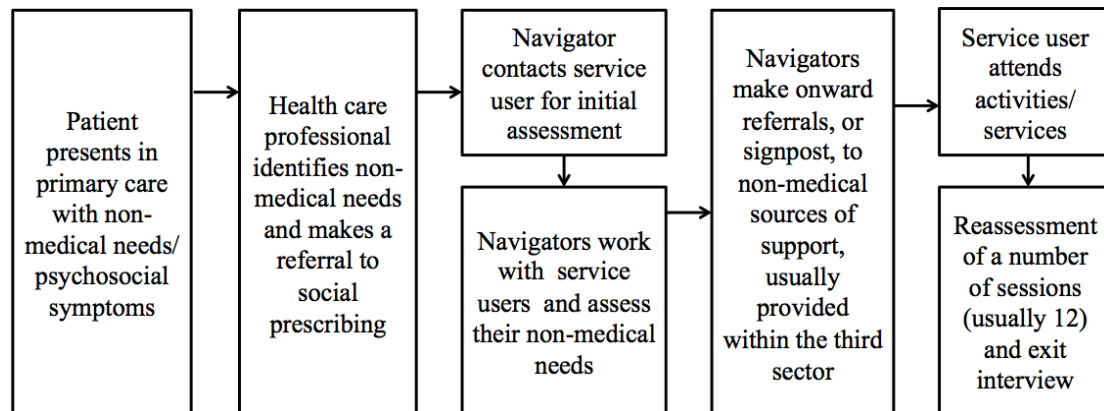


Figure 3: Summary of Luton social prescribing pathway

SP holistic models are also considered to be complex public health interventions. ‘Complex interventions’ are defined as interventions comprising multiple interacting components, which act in synergy to produce change (Moore *et al.*, 2014). Special challenges for evaluators of complex interventions are related to the difficulty of standardising the delivery of the intervention, their sensitivity to features of the local context, the organisational and logistical difficulty of applying experimental methods to service change, and the length and complexity of the causal chains linking the intervention with outcome (Craig *et al.*, 2008).

3.3.4 Supporting information technology infrastructure

It was initially planned to include a card system, supported by a cloud database, in the Luton SP programme. Each referred patient was meant to receive a ‘My Activity Card’ during the first appointment with navigators. Accredited service providers would be provided with smart phones, with a Luton SP application installed, to which service users could tap their card when attending the referred services. The card system would support complete and standardised data collection and allow service users and providers to monitor the attendance and progress of service users. Figure 4 summarises the activity card based process as initially planned.

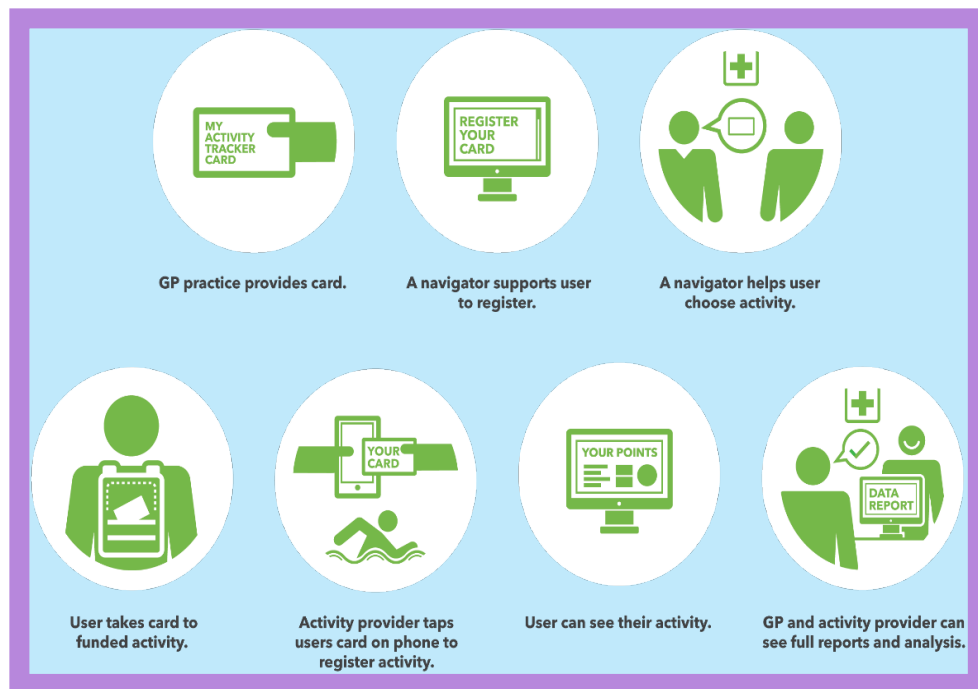


Figure 4: The use of the activity card in the Luton SP programme (Luton Borough Council, 2015b)

In addition to this supporting card system, an information technology (IT) platform facilitating referrals (i.e., electronic referrals), communication, and data sharing between frontline providers was planned. It was planned that frontline providers, managers, evaluators, and service users can log in to the online platform to review the information visible for them. Access to- and visibility of- information would depend on the user log in information, in order to protect the privacy of service users. The IT platform was also meant to support complete and consistent data collection across different time points (including long-term follow ups), as well as the management and storage of data.

An external company was contracted to develop the supporting IT infrastructure for the Luton SP model. From the beginning of the implementation stage (beginning 2015), the steering group and implementation team have invested time and resources in the development of the IT platform and card system to support the delivery and evaluation of the Luton SP programme. However, the development of the IT platform and card system took longer than anticipated and significantly delayed the start of the SP programme. In order to prevent further delays and start referring patients to the programme in January 2016, the steering group developed a ‘paper-based’ version of the Luton SP programme.

In the paper-based version of the SP programme, GPs made referrals to the SP programme on a paper based referral form, which they left at reception for the navigators to pick up. Due to

the lack of the IT platform, there was no standardised way of referrals from navigators to service providers in the third sector. Navigators referred service users onwards via phone, email, or letter. In order to track the attendance of service users, navigators had to rely on the service user's reports or contact the service providers directly. Navigators collected data from service users, pre- and post-intervention, on paper, using a number of different data collection forms. In order to allow the quantitative evaluation of service user outcomes, navigators were required to enter the collected data in a Microsoft Excel form. Initially, the paper-based version of the Luton SP model was developed as a short-term solution until the planned IT platform and card system were ready to use. However, the completion of the supporting IT infrastructure was more time consuming and challenging than initially anticipated. The reasons for the experienced delays will be explored in more detail in this study. However, the IT platform was ready to be tested by the users at the end of the pilot period (February 2018) and therefore never used in practice. The development of the card system was not completed till the end of the pilot period.

3.4 Chapter Summary

This chapter has provided an overview of the demographics of Luton, local population needs, and health and life expectancy inequalities. In addition, it has highlighted how SP could help to address these local inequalities and population needs. It then provided a description of the Luton SP programme, including its funding source, duration, aims, pathway, target groups, and the planned IT platform. It finishes with a description of the experienced challenges in relation to the development of a supporting IT infrastructure for the Luton SP programme, and how the alternatively developed 'paper-based' version of the programme worked in practice.

4 Chapter 4: Conceptual foundations

4.1 Introduction

SP is based on horizontal integration and an example for integrated care initiatives. This chapter begins with a discussion about the challenges of conceptualising integrated care. The discussion in this chapter will be focused on SP as a specific example of integrated health and social care interventions. It then explores the Rainbow model of integrated care (RMIC) as a theoretical underpinning for integrated health and social care interventions in primary care, and specifically for SP.

4.2 The challenge of conceptualising integrated care

As outlined in Chapter 2, integrated care has received increasing attention in the UK and globally, as a means to improve access, quality, and continuity of services in a more efficient way, especially for individuals with complex needs (e.g. multiple chronic conditions). Conceptual clarification of integrated care is needed to allow systematic and comparable descriptions of integrated care initiatives, understand the complex phenomenon of integrated care, learn from previous experiences, and to guide empirical research (Kodner and Spreeuwenberg, 2002; Axelsson and Axelsson, 2006; Valentijn, 2015).

4.2.1 Theories originating from other disciplines

Concepts and theories that originate from different disciplines (e.g. psychology, sociology, and organisational theory) have been used in the past to explain aspects of integration (Stein and Rieder, 2009). In this section, two examples of how sociological and organisational theories were applied to explore the integration of health and social services, and the weaknesses of this approach, are discussed. Organisational theories were often used in the literature to explore the implementation and functioning of integrated social and health care (Rhydderch *et al.*, 2004; Wallace, 2009; Chandler *et al.*, 2016). The traditional model of systems describes organisations as machines, including a constructor (the top manager) suggesting how the integral parts of an organisation are supposed to function and cooperate (Edgren, 2008). Change is seen as a linear and predictable process, controlled by managers from ‘outside’ (Edgren, 2008). Thus, the linear structure-process-outcome conceptualisation of integrated care is reflected in existing models and the literature (Tsasis *et al.*, 2013). Many integrated care models were grounded on the ‘traditional system view’ and industrial-quality improvement logic, in order to standardise the delivery of care based on top-down control strategies of change (Valentijn, 2015; Nicholson *et al.*, 2018). However, there is evidence that applying structural top-down strategies and modifications on the political and organisational level (macro-level) only, are insufficient to achieve sustainable integrated care (Tsasis, Evans

and Owen, 2012; Evans *et al.*, 2013; Grudniewicz *et al.*, 2018). In addition, scholars criticised traditional system thinking for overlooking the dynamic complexity of organisations (Edgren, 2008; Tsasis, Evans and Owen, 2012).

Given these identified weaknesses, attempts have been made to understand integrated care as a process-centred bottom-up approach and describe organisations as complex adaptive systems (CAS) (Chaffee and McNeill, 2007; Nugus *et al.*, 2010; Tsasis, Evans and Owen, 2012; Grudniewicz *et al.*, 2018). The CAS theory, which belongs to organisational theories, is increasingly applied to conceptualise integrated care (Nugus *et al.*, 2010; Tsasis, Evans and Owen, 2012; Chandler *et al.*, 2016; Grudniewicz *et al.*, 2018). It was also applied previously to support the development of SP programmes in primary care (Polley *et al.*, 2016). The CAS theory suggests that the interactions and relationships between actors within a system, across systems, and between systems and their environment are important, thus systems are not reduced to their individual components (Nugus *et al.*, 2010; Thompson *et al.*, 2016). It is assumed that the interactions of actors within and between systems and their interaction with external factors determine the overall behaviour of CASs and, hence, the implementation and functioning of integrated care initiatives (Tsasis, Evans and Owen, 2012; Thompson *et al.*, 2016). A key characteristic of CASs is self-organisation, meaning that systems organise from within through interactions between agents and their responses to external stimuli, i.e. surroundings, demand, and competing priorities (Chandler *et al.*, 2016). Self-organisation through interaction leads to sudden appearance of unpredicted phenomena (emergence), and the development of new behaviours and more complex structures (i.e. constant adaptations are happening) (Chaffee and McNeill, 2007; Chandler *et al.*, 2016). Forcing top-down control to integrate care can be intrusive and hindering agents to interact and adapt naturally to develop behaviours, networks, and structures necessary to integrate social and healthcare in a sustainable way (Tsasis, Evans and Owen, 2012). From the CAS theory view, external control has the potential to destabilise systems, and hence is perceived as counter-productive (Tsasis, Evans and Owen, 2012).

Previous studies indicated that an operational bottom-up integration approach is vital, especially for primary care in which services have traditionally been delivered in a mono-disciplinary practice (Tsasis, Evans and Owen, 2012; Valentijn, 2015). However, this does not imply that top-down strategies and modifications at the system, organisational, and political level are unnecessary (Valentijn, 2015; Grudniewicz *et al.*, 2018; Nicholson *et al.*, 2018). Previous studies showed that integration plays complementary roles on the micro (clinical integration), meso (professional and organisational integration), and macro (system integration) level (for definitions of the terms see section 4.2.2) (Valentijn, 2015; Wodchis *et*

al., 2015; Evans *et al.*, 2016; Nicholson *et al.*, 2018). Thus, scholars highlight the need to seek alignment of both structural top-down and operational bottom-up strategies to achieve successful and sustainable integrated care (Valentijn, 2015; Wodchis *et al.*, 2015; Evans *et al.*, 2016; Angus and Valentijn, 2018; Nicholson *et al.*, 2018). As the CAS theory focuses on meso level integration and a bottom-up approach exclusively, it neglects the integration on the micro and macro level, the connection between these three levels, and the possibility to explore a top-down or two sided (bottom-up and top-down) integration approach (Valentijn *et al.*, 2013).

A previous study on SP has applied the social capital theory (i.e. a sociological theory) to understand the quality of the relationships between health care professionals and third sector practitioners (White, Cornish and Kerr, 2017). In this study, the social capital theory was applied to investigate the relationships between the two stakeholder groups, by considering their understandings, beliefs, and values (cognitive dimension), mutual trust, co-operation, and reciprocation (relational dimension), and network ties (structural dimension) (White, Cornish and Kerr, 2017). Previous research found that the integration at the provider level is key for the successful implementation and functioning of SP and other initiatives based on horizontal integration (Brandling and House, 2007; RAND Europe, 2012). However, exploring professional integration (i.e. integration on the meso level) in isolation, neglects the relationships between other key stakeholders involved in the implementation and delivery of integrated programmes, macro-level actions such as data linkages or payment reform, and the inherent multifaceted nature and dynamic complexity of implementing and providing integrated social and health care (Valentijn, 2015; Angus and Valentijn, 2018). The Medical Research Council (MRC) advises against focusing narrowly on theories from single disciplines to evaluate complex interventions, such as SP, that require changes at various levels (e.g. population, individual, professional, organisational, system level change) (Moore *et al.*, 2014).

Valentijn *et al.* (2013) argue that the lack of a comprehensive framework taking the principles of primary care, as well as the micro, meso, and macro level of integration, the interrelationship between these levels, and multiple stakeholder perspectives into account, hampers a systematic understanding and comparable evaluations of integrated care in primary care. To address this knowledge gap, Valentijn *et al.* (2013) developed a conceptual framework for integrated care from a primary care perspective, called the Rainbow Model of integrated care (RMIC). The RMIC provides a theory that underpins how integrated care efforts (clinical, professional, organisational, and system integration) act at different levels (micro, meso, and macro), and can be defined from multiple stakeholder perspectives (e.g.

patients, professionals, managers, decision makers, and policy makers), taking the principles of primary care into account (Valentijn, Biermann and Bruijnzeels, 2016). The RMIC combines the concepts of primary care with the different dimensions of integrated care, and thus considers the multifaceted and complex nature of integrated social and health care interventions, such as SP, implemented in primary care (Valentijn *et al.*, 2013). Valentijn *et al.* (2016) developed a revised version of the RMIC, in which the Triple Aim outcome domains are included within the RMIC (Figure 5). This revised RMIC is believed to provide an appropriate theoretical foundation to explore SP in this study, and is discussed in more detail in the following section.

4.2.2 The Rainbow Model of integrated care

The overarching conceptual model including the RMIC with the Triple Aim framework by Valentijn (2016) is used as a theoretical framework to explore SP in this study (Figure 5).

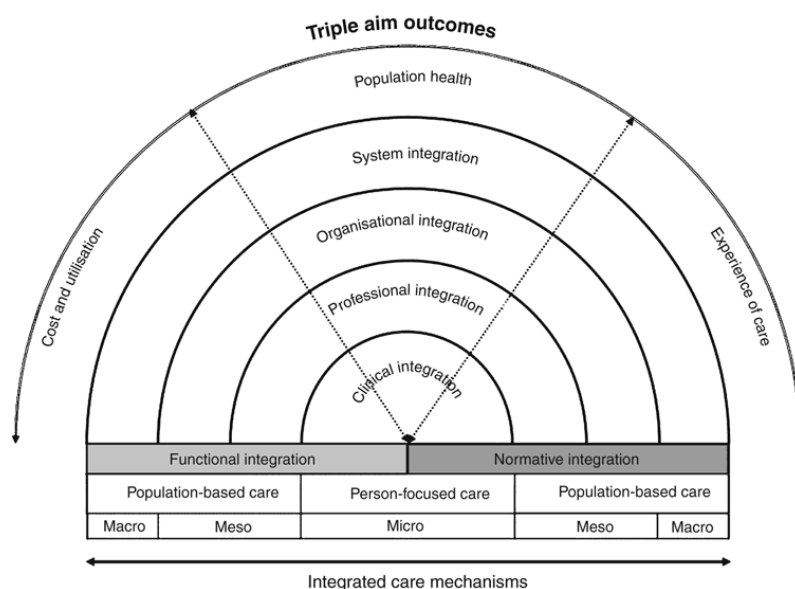


Figure 5: The revised RMIC (Valentijn, 2016)

In the overarching conceptual model (Figure 5) the Triple Aim outcome domains: (i) cost & utilization, (ii) population health, and (iii) experience of care, are visualised in the outer bow of the model (Berwick, Nolan and Whittington, 2008). In 2008, Donald Berwick, Thomas Nolan, and John Whittington published the Triple Aim framework to guide healthcare improvement initiatives and to focus on three goals simultaneously: Reducing per capita cost of care for populations, improving the health of populations, and improving the individual experience of care (including quality and satisfaction) (Berwick, Nolan and Whittington, 2008). The outer bow of the model (Figure 5) visualises that the three outcome domains are

interrelated (Valentijn, Biermann and Bruijnzeels, 2016). The Triple Aim has been used to guide numerous improvement initiatives in the United States (US), and is increasingly applied by healthcare practitioners, researchers, and policy makers worldwide (Whittington *et al.*, 2015; Mery *et al.*, 2017). In recent years, the Triple Aim framework is increasingly explored in relation to integrated care (Hildebrandt *et al.*, 2015; Boesveld *et al.*, 2017). Valentijn *et al.* (2016) suggested that all three aims should be considered in an outcome evaluation of integrated care initiatives, however due to limited resources and time to complete this doctoral thesis, this study focused on population health and wellbeing only.

The inner bow of the overarching conceptual model (Figure 5) represents the initial RMIC. In the RMIC the definition of integrated care of Leutz (1999) was used to define integration, and primary care was defined as stated in the Alma Ata Declaration 1978 (Table 1) (Valentijn *et al.*, 2013). The concepts of primary care mentioned in the declaration of Alma-Ata, namely inter-sectorial collaboration in dealing with community problems and equity on the basis of need are in line with the concepts of integrated and patient-centred care (Valentijn *et al.*, 2013). Moreover, the functions of primary care, namely providing the first contact with the health system, as well as continuous, comprehensive, and coordinated care make primary care a central hub for integrating health and social services (Valentijn *et al.*, 2013). The arrows starting in the RMIC in the inner bow, and ending in the Triple Aim outcome domains in the outer bow (Figure 5), visualise that achieving the Triple Aim outcomes require different dimensions of integration structured around the micro, meso, and macro level, involving co-creation and collaboration across all key stakeholders (e.g. patients, professionals, managers, policy-makers), as well as a population and health focused view (Valentijn, Biermann and Bruijnzeels, 2016). It is key to note that achieving the Triple Aim outcomes requires the uptake of an integrated care initiative by the target population and adherence to it, too (Chaudoir, Dugan and Barr, 2013; Moore *et al.*, 2014). Therefore, it is assumed that the dimensions of integrated care, collaboration across stakeholders, and principles of primary care can influence the patient uptake and adherence to an integrated care initiative, too (Valentijn *et al.*, 2013; Moore *et al.*, 2014). In line with the MRC guidance and critical realist paradigm (see Chapter 4 for more details on critical realism) the revised RMIC encourages the combination of outcome and process evaluations, to understand how and why observed effects of the specific intervention occurred (Moore *et al.*, 2014). In the MRC guidelines, the term ‘process evaluation’ is defined as a study that aims to examine implementation, mechanisms of impact, and contextual factors to understand the functioning and outcomes of an intervention (Moore *et al.*, 2014). Thus, a process evaluation explores the implementation, setting, and patient/service user interaction with the intervention and can inform the interpretation of outcomes (Oakley *et al.*, 2006).

Table 1: Definitions of integrated care and primary care

Concept	Definition
Integrated care: Leutz 1999 (Leutz, 1999)	The search to connect the healthcare system (acute, primary medical and skilled) with other human service systems (e.g., long-term care, education and vocational and housing services) to improve outcomes (clinical, satisfaction and efficiency).
Primary care: WHO Alma Ata Declaration (1978) (World Health Organization, 1978)	Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part of both the country's health system, of which is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.

The elements and dimensions outlined in the revised RMIC (Figure 5) are discussed in more detail in the following sections.

A person and population health focused view

Enclosed in the definition of primary care is the person-focused (also referred to as patient-centred) and population-based care view (Table 1) (Valentijn *et al.*, 2013). Person-focused care is based on personal preferences, values, and medical, psychological, and social needs of individuals (Valentijn *et al.*, 2013). Population based care means that services should be based on the needs and characteristics of populations (including health, economic, social, and environmental needs), to promote equal health and wellbeing (Valentijn *et al.*, 2013). Both approaches recognise the relationship between social and health problems, and acknowledge the wider determinants of health. Thus, person-focused and population-based care approaches in primary care are especially important for linking health and social systems (i.e. for SP). In

the RMIC, the person-focused and population-based care provides the foundation of the conceptual framework.

Dimensions of integrated care

The revised RMIC constitutes the different dimensions of integrated care. Integration at the macro level (system), meso level (organisational and professional), and micro level (clinical) is essential to implement integrated care initiatives, such as SP, and to achieve successful outcomes (Valentijn *et al.*, 2013; Valentijn, 2015). In addition, the integration across these dimensions can influence the uptake and adherence to integrated care services (Brennan *et al.*, 2013; Killingback, Tsofliou and Clark, 2017).

The macro level: System integration

System integration refers to political arrangements and the alignment of physical space, rules, processes, structures, and policies between integrated systems, to deliver integrated care for the benefit of the general populations (Valentijn *et al.*, 2013; Valentijn, Biermann and Bruijnzeels, 2016). Determinants of system integration relevant for SP are, for example, available resources (e.g. funding through the Better Care Fund and shared physical space), engagement of stakeholders (e.g. primary care staff, patient organisations, community organisations), and the political, economic, and social climate in the environment where integration takes place (Valentijn, Boesveld, *et al.*, 2015). As discussed previously in this chapter, previous studies have highlighted the importance of system integration to implement integrated social and health care services, such as SP (Valentijn, 2015; Wodchis *et al.*, 2015; Grudniewicz *et al.*, 2018; Nicholson *et al.*, 2018).

The meso level: Organisational and professional integration

Organisational integration refers to the extent of which services are produced and delivered in a linked-up fashion (Valentijn *et al.*, 2013). Differences in culture, language, backgrounds, bureaucratic structures, professional roles and responsibilities, organisational visions, and regulations between social and health organisations can complicate organisational integration (RAND Europe, 2012; Cameron *et al.*, 2014). Previous studies found that organisational differences have hampered joint and integrated working between social and health services, and in turn hindered the implementation and delivery of integrated interventions (RAND Europe, 2012; Cameron *et al.*, 2014; Mackie and Darvill, 2016).

Professional integration refers to relationships between professionals within and between organisations (Valentijn *et al.*, 2013). Trust, shared understanding of roles, responsibilities, ethics, and language, as well as respect and communication can determine professional

integration (RAND Europe, 2012; Mackie and Darvill, 2016; White, Cornish and Kerr, 2017). The absence of professional integration has hindered the implementation and delivery of integrated health and social care previously (RAND Europe, 2012; Valentijn *et al.*, 2013; White, Cornish and Kerr, 2017). Effective joint-up working of front-line workers is also necessary to achieve the goals outlined in the Triple Aim framework (Valentijn, Biermann and Bruijnzeels, 2016).

Micro level: clinical integration

Clinical integration refers to the extent to which patient care services are coordinated across various professional, institutional, and sectorial boundaries in a system (Valentijn *et al.*, 2013). Established referral pathways across sectors and clear and simple referral forms can facilitate clinical integration. Clinical integration requires a person-focused perspective, professionals need to take account of both medical and non-medical (lifestyle related, social, and psychological) needs to improve the health and wellbeing of patients (Valentijn *et al.*, 2013). In SP, for example, health care professionals need to identify that a patient has non-medical needs and process a referral to a navigator of the SP programme. A key feature of clinical integration is that clients are proactively involved in the organisation and provision of care (Valentijn, Boesveld, *et al.*, 2015). Other key features involve the provision of clear and understandable information at the individual patient/service user level and the interaction between professionals (e.g. GPs, navigators) and patients/service users (Valentijn, Boesveld, *et al.*, 2015). These features are likely to affect patient uptake and adherence to SP (Brennan *et al.*, 2013; Killingback, Tsofliou and Clark, 2017).

Functional integration: Linking the macro, meso, and micro level

Functional integration includes the coordination of key support functions and activities, such as financial and information management, strategic planning, human resources, communication mechanisms, support systems, regular feedback, and quality improvement to enable integrated care (Valentijn *et al.*, 2013; Valentijn, Biermann and Bruijnzeels, 2016). The support functions are structured around the service delivery process to support smooth service delivery and partnership working across sectors (Valentijn *et al.*, 2013). An example for a support function that promotes communication and information management in SP is a shared IT system among front-line providers along the care continuum (e.g. GPs, navigators, and providers in the third sector) (Whitelaw *et al.*, 2017). The lack of a shared IT system tailored to the delivery process of an integrated health and social care initiative was identified as a significant barrier to collaborative working between front-line providers in previous studies (Ling *et al.*, 2012; Cameron *et al.*, 2014).

Normative integration: Linking the macro, meso, and micro level

Normative integration refers to the development and maintenance of a common frame of reference (e.g. shared goals, values, attitudes, and linking cultures) between organisations, professional groups, and individuals (Valentijn *et al.*, 2013). Examples of key features of normative integration are trust, visionary leadership, conflict management, and perceived need and purpose to collaborate (Valentijn, Boesveld, *et al.*, 2015). Normative integration is important to facilitate integration at all levels, and to achieve a sustainable service and shared goals towards the Triple Aim outcomes (Valentijn *et al.*, 2013; Valentijn, Biermann and Bruijnzeels, 2016). In addition, shared goals and visions among providers may promote patient uptake and adherence to integrated services. Previous research has found that normative integration is a critical enabler to the implementation of integrated care (Valentijn, Ruwaard, *et al.*, 2015; Valentijn, Vrijhoef, *et al.*, 2015; Valentijn, Biermann and Bruijnzeels, 2016).

Limitations of the revised RMIC

The inner bow of the revised RMIC was developed through an iterative process consisting of two steps: 1) a narrative literature review, and 2) group meetings and expert panels to synthesise the literature (Valentijn *et al.*, 2013). There are some methodological challenges to the development of the RMIC. Firstly, the non-existence of a common terminology and standardised terms in integrated care provides challenges to a comprehensive literature review informing the RMIC (Stein and Rieder, 2009; Valentijn, 2015). There may be studies and reports that would be relevant for the review, but could not be identified through the authors' searching efforts because of differences in terminology to describe integrated care. Potential publication bias may be another limitation of the literature review, as relevant studies on integrated care may exist but have not been accepted or submitted for publication or may not be publically available. Moreover, the evidence-base on integration is hampered by the lack of validated and standardised tools to measure integration (Valentijn *et al.*, 2013). Lastly, most of the available evidence on integrated care that informed the development of the RMIC is based on small pilots (Valentijn *et al.*, 2013).

4.2.3 The Rainbow Model of integrated care as a theoretical underpinning for this study

The RMIC model helped to understand and visualise that the implementation of SP, patient uptake/adherence, and achievement of service user outcomes require: (i) multiple dimensions of integration (clinical, professional, organisational, and system) which act at different levels (micro, meso, macro), (ii) are influenced by the principles of primary, population-focused, and patient-focused care, and (iii) can be defined from multiple stakeholder perspectives (e.g.

patients, front-line providers, managers, and policy-makers). The RMIC also guided the methods of this research study in various ways. Firstly, it informed the primary outcomes of the systematic review (Objective 1), as the multifaceted and complex nature of SP was considered when facilitators and barriers to implementation were identified from included studies. Moreover, information on how and why service user outcomes were achieved were included in the narrative analysis of service user outcomes in the systematic review (Objective 1). Thirdly, the RMIC guided the primary research methods of this study, as multiple stakeholder groups were included in the study to capture their perspectives of facilitators and barriers to implementation (Objective 2) and factors affecting patient uptake and adherence (Objective 3). Furthermore, service user outcomes were not explored in isolation, as the factors and mechanisms that contributed to the experienced outcomes were considered (Objective 4). The findings of this study were also discussed in relation to the RMIC in Chapter 10 of this thesis.

4.3 Chapter summary

This chapter has discussed the challenges of conceptualising integrated social and healthcare initiatives, such as SP. It discussed the limitations of using theories originating from other disciplines to conceptualise integrated social and health care programmes and explained why these approaches fail to consider the multifaceted and complex nature of integrated care initiatives. It then presented the conceptual framework (RMIC) developed by Valentijn *et al.* (2013), explained why the RMIC is appropriate to conceptualise SP, and how it informed the current study.

5 Chapter 5: Methodology

5.1 Introduction

This chapter restates the aim and objectives of this study. It then discusses and compares the positivist, interpretivist, and critical realist paradigms and discusses why critical realism provides an appropriate philosophical basis for this study. The last section of this chapter provides a rationale for utilising a mixed method approach and a visual representation of the convergent parallel mixed-methods design for this study.

5.2 Research aim and objectives

5.2.1 Research aim

To develop a framework of knowledge to advance the implementation, practice, and evaluation of SP.

5.2.2 Research objectives

The objectives of this study were:

1. To identify and synthesise evidence on:
 - Factors that facilitate and hinder the implementation of SP programmes in the UK
 - The impact of SP on service users in the UK
2. To identify the factors that facilitate and hinder the implementation of the Luton SP programme
3. To explore the factors that affect patient uptake and service user adherence to the Luton SP programme
4. To assess and explore service user outcomes of the Luton SP programme

5.3 Philosophical stances of research

5.3.1 Competing paradigms in social sciences

In research, the paradigmatic positioning relates to a researcher's understanding of the nature of knowledge (their epistemological standpoint) and of reality (their ontological standpoint), also referred to as philosophical stance, which influence research methodology and methods (Bowling, 2014). Consistency between the overall study aims, research questions, methodology, methods, and the philosophical stance of the researcher is necessary to protect argumentative coherence in a research study (Proctor, 1998).

The commonest paradigm split in social sciences has been between the positivist and interpretivist philosophy, the so called 'paradigm war' (Johnson and Onwuegbuzie, 2004;

Glogowska, 2011). As suggested by Wolfe (1997) the split between the positivist and interpretivist paradigm can be seen as the two faces of the social sciences. A positivist paradigm maintains that objective knowledge can be produced through rigorous methodology and that reality is fixed and independent (Johnson and Onwuegbuzie, 2004; Glogowska, 2011). Quantitative research has been linked with the positivist paradigm (Glogowska, 2011). In contrast, an interpretivist paradigm maintains that knowledge is socially constructed and that reality is ultimately subjective (Saks and Allsop, 2007). Qualitative research has been linked with the interpretivist paradigm (Glogowska, 2011).

5.3.2 The positivist paradigm

Positivism is a recurrent theme and has been evolved in the history of western thought from the Enlightenment to the present day (Cohen, Manion and Morrison, 2007). Nevertheless, it is historically associated with philosopher Auguste Comte who had the idea to transform society on the basis of natural science, and thus cemented positivism in human sciences in the 19th century (Cruikshank, 2012). Since today, positivism remains a dominant approach to research in the social world, and shapes methodology and methods of research on health and healthcare (Morgan, 2007; Bowling, 2014).

An overview of the positivist paradigm

Positivists believe that reality is fixed, objective, and exists independently of social actors (Bryman, 2008; Lipscomb, 2010). Thus, from a positivist perspective, it is possible to observe, measure, and test reality using a deductive approach and the principles of natural scientists (Johnson and Onwuegbuzie, 2004; Bowling, 2014). Deduction refers to the testing of a priori formulated theories and hypotheses through logical processes of evidence gathering (Glogowska, 2011). Furthermore, positivists believe that a reliable and valid body of absolute knowledge can be established, which is value-free and unbiased (Johnson and Onwuegbuzie, 2004; Bowling, 2014). Thus, positivists believe that produced knowledge is independent from the political, environmental, and historic context (Johnson and Onwuegbuzie, 2004). Therefore, positivism commits to an empiricist epistemology, which holds that knowledge only be obtained by means of observation and experiment (Cohen, Manion and Morrison, 2007). For positivists, therefore, things exist only if they can be measured or observed (Wainwright and Forbes, 2000). Given the denial of non-observables, positivist researchers are not concerned with measuring meanings of situations or attitudes, feelings, emotions, and experiences relying on subjective reports, as they cannot be measured in a scientific and objective way (Lipscomb, 2010). In positivist research, the researcher and researched are independent entities, therefore the researcher has the role of a detached and objective observer (Cohen *et al.*, 2007).

Positivist methodology is directed at hypothesis testing to establish relationships and causality, to formulate laws, and make time- and context-free generalisations of results (Johnson and Onwuegbuzie, 2004; McEvoy and Richards, 2006; Creswell, 2009). Thus, a quantitative and deductive approach is undertaken (Glogowska, 2011). Positivists consider their methodology as value free, which allows them to claim that generated knowledge is similarly value free and objective (Johnson and Onwuegbuzie, 2004; Glogowska, 2011).

Discussion of the positivist paradigm in relation to the present study

A systematic review is a form of a literature review that involves identifying, synthesising, and assessing all available research evidence to generate a robust, empirically derived answer to a research question (Mallett *et al.*, 2012). Systematic reviews rely on transparent, rigorous, objective, and reproducible research methods (Mallett *et al.*, 2012). Since the 1970s, systematic reviews are used in medical and natural sciences to examine the effectiveness of healthcare interventions and support the practice of evidence-based medicine (Mallett *et al.*, 2012). RCTs are considered as the ‘gold standard’ to assess the effects on interventions, thus in the past systematic reviews focused on synthesizing quantitative data (Askie and Offringa, 2015). Therefore, traditionally, systematic reviews are based within the positivist paradigm and are on the top of the hierarchy of evidence for the effectiveness of interventions and treatments (Figure 6) (Togerson, 2003; Akobeng, 2005). However, from these beginnings, the methods of systematic reviews have been developed to address aspects other than effectiveness of healthcare to inform policy and practice at different stages (Atkins *et al.*, 2012; Askie and Offringa, 2015). Therefore, different study types, including non-randomised studies and qualitative studies are increasingly included in systematic reviews to generate robust evidence (Atkins *et al.*, 2012; Mallett *et al.*, 2012; Askie and Offringa, 2015).

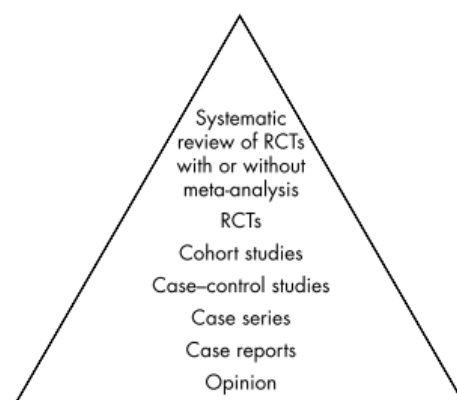


Figure 6: Hierarchy of evidence for questions about the effectiveness of an intervention or treatment (Akobeng, 2005)

In line with a recent increase in the interest of mixed methods in primary research, mixed methods systematic reviews emerged as a distinct category in secondary research (Tashakkori and Teddlie, 2010; Atkins *et al.*, 2012; The Joanna Briggs Institute, 2014). A mixed methods systematic review is defined as a review that combines findings of qualitative and quantitative studies within a single review (Tashakkori and Teddlie, 2010). Over the last decades, health service research increasingly relates to qualitative, as well as quantitative research (Lloyd Jones, 2004). For example, previous studies showed that approaches to understand factors that may facilitate or hinder the implementation of an intervention, experiences, underlying mechanisms of change, and outcomes are based on both qualitative and quantitative research (e.g. Curry *et al.*, 2013; Greaves *et al.*, 2013; Pawson and Tilley, 1997; Greenfield *et al.*, 2014; Ralston *et al.*, 2004).

From a positivist perspective, the synthesis of qualitative research is contested on the basis of epistemological and ontological concerns (Okoli and Molson, 2015). Although the overall aim of a 'traditional' systematic review is to produce an overall pooled estimate, the systematic review in the present study does not aim to arrive at a single truth and to provide definitive knowledge. Instead, the aim of the present systematic review was to develop an evidence base accepting multiple perspectives and views of reality derived from different research studies. The importance of considering multiple perspectives and views is demonstrated by the complexity and multifaceted nature of integrated social and healthcare interventions, outlined in the RMIC (Figure 5). However, the aim of this review is not in line with the positivist tradition (Okoli and Molson, 2015). Therefore, the positivist paradigm does not provide a ground for the mixed methods systematic review of the study (Objective 1).

A major criticism of the positivist approach is that it does not provide the means to explore experiences and emotions where the ontological reality relies on subjective or non-observable reports (Saks and Allsop, 2007; Lipscomb, 2010). Positivists argue that researchers cannot make claims about processes, mechanisms, or social structures that cannot be observed (McEvoy and Richards, 2006). However, some authors argue that the complexity of the social world cannot be captured when reducing phenomena to quantifiable variables (Pawson and Tilley, 1997; Wainwright and Forbes, 2000). As this study aims to identify factors that hinder and facilitate the implementation of SP (Objective 2), explore factors that affect patient uptake and adherence to SP (Objective 3), as well as service user outcomes (Objective 4), based on subjective reports that might not be quantitatively observable, a purist positivist approach does not provide an appropriate philosophical underpinning for the qualitative research of this study.

To assess the outcomes for service users of the SP programme, quantitative methods are used (Objective 4). However, it is expected that contextual factors affect intervention outcomes, therefore observed outcomes of SP can vary across different settings and over time (Moore *et al.*, 2014). Hence, the unique interactions between the local context and the SP programme may preclude the achievement of the aim of positivist research, to generalise results over time and across populations and contexts (Johnson and Onwuegbuzie, 2004; Zachariadis, Scott and Barrett, 2013).

Another challenge to the present study is that positivist research aims to establish a cause and effect relationship among distinct events, i.e. that event 'A' causes 'B' (Zachariadis, Scott and Barrett, 2013). In clinical interventions the causal chain between a drug or a surgical procedure and the outcome is relatively short and simple (Victora, Habicht and Bryce, 2004). However, in complex interventions such as SP, the causal chain is more complex (Victora, Habicht and Bryce, 2004; Oakley *et al.*, 2006). It would be an over-simplification to conclude that SP programmes, per se, cause, for example, an increase in physical activity. Therefore, the underlying concepts of a positivist approach (i.e., causation and generalisation of results) are not in line with the aims of the present quantitative analysis of service user outcomes (Objective 4).

5.3.3 The interpretive paradigm

Although the positivist paradigm maintained its dominance in the 20th century, the interpretive paradigm emerged in the social sciences in the 1960s and 1970s (Saks and Allsop, 2007). Scientists and scholars such as Kuhn, Bronowski, and Popper challenged the dominant paradigm because of its mechanistic and reductionist view of nature, which defines life in objective measurable terms rather than inner experience (Cohen, Manion and Morrison, 2007).

An overview of the interpretive paradigm

The interpretive paradigm includes a wide range of diverse philosophical positions, including symbolic interactionism, phenomenology, ethnomethodology, and hermeneutics (McEvoy and Richards, 2006). The following discussion will focus on the commonalties of these interpretive positions, rather than on their differences. There is a fundamental ontological assumption that reality is individually constructed by associating meaning with objects, events, or actions and through social interactions (Willis, 2007; Bryman, 2008; Glogowska, 2011). Thus, in contrast to positivists, interpretivists argue that reality is not objectively measurable and that multiple constructed realities exist alongside each other (Johnson and Onwuegbuzie, 2004; Bryman, 2008).

From an interpretive perspective, knowledge is firstly, socially constructed through the interaction between humans, language, and the world and secondly, developed and transmitted in a social context (Crotty, 1998). Thus, for interpretivists the world does not exist independently of human knowledge of it (Murphey and Dingwall, 1998). In contrast to positivists, interpretivist researchers claim that knowledge cannot be value free and objective, as researchers make value laden decisions, based on their personal experiences and beliefs, throughout the whole research process and position their work in a specific context (Edge and Richards, 1998; Johnson and Onwuegbuzie, 2004).

Furthermore, interpretive researchers reject the viewpoint of the detached, objective, and independent observer (Johnson and Onwuegbuzie, 2004; Cohen, Manion and Morrison, 2007). A feature of interpretive research is that researchers interact with individuals to understand their experiences in specific contexts and interpretations of the world (Cohen *et al.*, 2007). The emphasis is on partnership between the researcher and the researched, as both are shaping the research process, and a relationship based on equality, rather than a one-sided, unidirectional view of the researcher as powerful observer and the research participant as less powerful subject (Cohen *et al.*, 2007).

Interpretivists agree that the social world can be understood only from the standpoint of the individuals who are a part of the phenomena being investigated (Cohen, Manion and Morrison, 2007). Beliefs that human behaviour is governed by general, universal laws and characterised by underlying regularities are rejected (Cohen *et al.*, 2007). Therefore, interpretive methodology is directed to explore the experiences of individuals in a particular context and time and the subjective meanings that could explain the process of decision-making (Edge and Richards, 1998; Saks and Allsop, 2007). Therefore, interpretivist research aims to provide an in-depth understanding of phenomena, rather than establishing relationships and universal truth (McEvoy and Richards, 2006; Saks and Allsop, 2007). Furthermore, from an interpretivists perspective, time and context free generalisations are neither desirable nor possible (Johnson and Onwuegbuzie, 2004).

Discussion of the interpretivist paradigm in relation to the present study

Although systematic reviews are originally associated with positivism, the development of review and synthesis methodologies applicable to qualitative research have increased over the past decades (Lloyd Jones, 2004; Mallett *et al.*, 2012; Askie and Offringa, 2015). However, as the present systematic review aims to establish an evidence base based on qualitative and quantitative studies, it is not in line with a pure interpretivist approach to research.

The interpretive paradigm allows researchers to view interventions such as SP through the perceptions and experiences of different stakeholders and service-users. Interpretivism accepts multiple, and possibly contradictory, realities which allows the development of a comprehensive understanding of SP programmes (Glogowska, 2011). As interpretivism values subjectivity, it provides a context to gather qualitative data based on subjective reports, including non-observable structures and processes.

An advantage of qualitative research is that it allows researchers to explore new ideas, challenges, and opportunities of the relatively new approach of SP in primary care, rather than testing pre-existing hypotheses or theories (Saks and Allsop, 2007). Furthermore, the flexible nature of qualitative research enables researchers to adjust their approach in response to emerging themes, and thus discover unintended consequences or findings that contradict initial assumptions and introduce innovative thinking (Saks and Allsop, 2007). This is an advantage over the positivist research in which a strict study protocol is followed and only pre-defined events of interest are considered.

However, interpretivist research focuses exclusively on subjective accounts and interpretations to explore the lived experiences of study participants. Their ontological standpoint is restricted to the understanding of subjective meaning of individuals (McEvoy and Richards, 2006). Thus, contextual factors, social structures, networks, or mechanisms that are unnoticed but may enable or constrain the actions of individuals and influence their experiences are excluded. As the present study aims to go beyond the lived experiences of stakeholders to explore contextual factors that could influence the implementation of SP, patient uptake and adherence, and outcomes (Objective 2, 3, and 4), the interpretivist approach appears to be too restrictive for the present study.

Another conflict emerges between the interpretive methodology and the aim of the study to assess the outcomes of SP for service users quantitatively (Objective 4). Although the study does not follow the purist positivist approach to establish a generalisable cause-effect relationship between SP and service user outcomes, it does aim to assess whether a change happened in mental wellbeing and energy expenditure after the intervention. Thus, the quantitative approach to achieve the objectives is not in line with the purist qualitative approach of the interpretive paradigm.

Interpretivist research has been criticised for producing specific qualitative data, which cannot be generalised to the wider population and has limited transferability to other contexts and settings (Scotland, 2012). As generalisation is useful for policy making, it was argued that

there is little value in funding qualitative research, as findings cannot be generalised to larger populations or transferred into other contexts (Saks and Allsop, 2007). However, it is increasingly recognised that qualitative research is equally important for policy making because it provides information on why an intervention is successful or not, how, and in which contexts it may work (Bonell *et al.*, 2012; Moore *et al.*, 2014). Based on the MRC guidelines 2014 and the RMIC, this study assumes that linking qualitative and quantitative data yields the most informative results to understand SP in UK primary care, and thus goes beyond the traditional purist qualitative approach to inform policy, practice, and further research (Moore *et al.*, 2014).

5.3.4 Critical realism

Critical realism is a relatively contemporary philosophy of science that offers an alternative to the established purist paradigms of positivism and interpretivism (Houston, 2001; McEvoy and Richards, 2003). The Indo-British philosopher, Roy Bhaskar, developed critical realism in the 1980s in collaboration with British social theorists, including Margaret Archer, Mervyn Hartwig, Tony Lawson, Alan Norrie, and Andrew Sayer (Gorski, 2013). The critical realism movement is centred in the UK but has followers throughout Europe, Asia, and the Americas (Gorski, 2013). Although it is a relatively new philosophical stance in health research, it is becoming increasingly influential (McEvoy and Richards, 2006; Bertotti *et al.*, 2017).

An overview of critical realism

The ontological assumptions of critical realism is that the world is a stratified open system (Zachariadis, Scott and Barrett, 2013). Critical realism assumes an interrelated stratified ontology divided into three domains: the real (those structures and mechanisms that generate phenomena), the actual (those aspects of reality that occur but may not be observable), and the empirical (those aspects of reality that can be directly or indirectly experienced and observed) (McEvoy and Richards, 2006). Therefore, likewise positivists, critical realists support the idea of a reality that exists independently of human knowledge and perception of it (Archer *et al.*, 1998). However, from a critical realist perspective, it is impossible to have immediate access to this reality and to observe all aspects of it directly (Zachariadis, Scott and Barrett, 2013). The domain of the 'real' includes structures and processes with causal powers and liabilities, which result in generative mechanisms that may not be visible or empirically observable (Zachariadis, Scott and Barrett, 2013). However, their potentialities may still exist whether they are exercised or unexercised and independently of human perception or ability to know them (Bhaskar, 1979). According to Lawson (Lawson, 1997 p. 21):

‘A mechanism is basically the way of acting or working of a structured thing...Structured things (physical objects or social processes) possess causal (or emerged) powers which, when triggered or released, act as a generative mechanism to determine the actual phenomena of the world.’

In contrast to positivist philosophers, Bhaskar argues that reality includes structures that have effects upon things and is not confined to observable things (Porter and Ryan, 1996). Thus, critical realists permit unobservable structures and mechanisms ontological veracity.

Given that the ontological domains are interrelated, the domain of the ‘actual’ is a subset of the real and includes events generated by mechanisms that might or might not be detectable by human observers (Zachariadis, Scott and Barrett, 2013). Finally, the domain of the ‘empirical’ includes the subclass of observable, noticed, and experienced events and changes, and is considered only a small part of reality (Zachariadis, Scott and Barrett, 2013). Given that critical realists believe that mechanisms and structures interact in contingent ways to produce change at the level of observable events, rather than following a set order, they see the world as an open system (Cruickshank, 2012). Therefore, it is believed that observable phenomena, human actions, and behaviours are embedded in a wide range of mechanisms, social processes, and structures (Bertotti *et al.*, 2017). Figure 7 shows an outline of the discussed critical realist ontology.

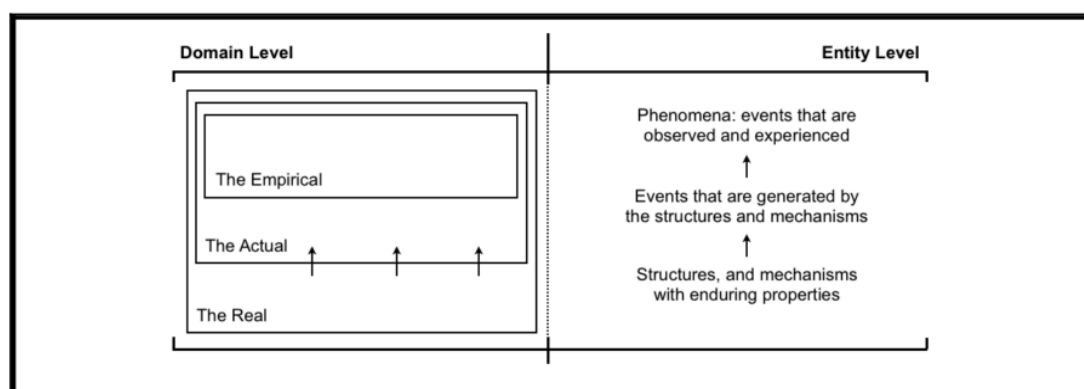


Figure 7: The stratified Ontology of critical realism (Zachariadis, Scott and Barrett, 2013)

Bhaskar draws a distinction between reality and the accepted knowledge of that reality (Cruickshank, 2012). Although reality is believed to be independent of knowledge and perception (intransitive domain), the generation of knowledge about that reality is socially derived and a human activity that is dependent on theories, methods, models, and techniques used by researchers at a certain time and place (Lipscomb, 2010; Zachariadis, Scott and

Barrett, 2013). Therefore, it is believed that scientific knowledge is fallible and open to criticism, revision or replacement (transitive domain) (Lipscomb, 2010; Cruickshank, 2012). From a critical realist perspective, therefore, even though researchers may replace their theory about a phenomenon (transitive domain), it does not change the reality about a phenomenon (intransitive domain). For example, even though the 'flat earth' theory was believed and eventually replaced with the 'round earth' theory (transitive), the shape of the earth did not change (intransitive). Hence, critical realists believe that knowledge is articulated in two dimensions: 'it is a socially produced knowledge of a neutral (human independent) thing' (Archer *et al.*, 1998 p.65). The distinction between the intransitive and transitive domain points out that despite ontological realism, epistemological relativism is adopted (Archer *et al.*, 1998). Therefore, critical realists view the process of scientific knowledge as historically emergent, political, and imperfect (Smith, 2006). Moreover, it is believed that the mechanisms that produce phenomenon need to be taken into account, as observations and correlations between variables alone cannot produce knowledge of a phenomenon (Zachariadis, Scott and Barrett, 2013). The critical realist epistemology finds some common ground with interpretivism in that transient knowledge is socially constructed and not objective.

Contrary to interpretivism and in common with positivism, critical realism recognises the concept of causality. The positivist philosopher David Hume argues that the empirical concept of causation invokes the observation of a constant conjunction of observable events (Hume, 1978). This interpretation excludes anything unobservable, such as social structures, conditions, and underlying mechanisms. Critical realists argue that reducing the notion of causation to observable events is inadequate and provides a thin and superficial explanation of causal sequences (Connelly, 2007). Critical realists' account of causation differs markedly from that of positivists, as it is not about a causal relationship between two (observable) events. It refers to the identification of generative mechanisms that may cause an observable event in a specific context (Collier, 1994; Lipscomb, 2010). Therefore, critical realists refer to causal tendencies that are produced by underlying mechanisms, rather than to regular cause and effect relations between specific recurrent events (Connelly, 2007). Hence, critical realism goes beyond documenting the relationship between empirically observable events by focusing on explanations of what may have caused these events (Okoli and Molson, 2015). Furthermore, as the occurrence of causal mechanisms is dependent on variable conditions (structures, powers, relations), researchers should identify the conditions in which mechanisms operate to produce situated analytical explanations of potential mechanisms involved in observable events (Zachariadis, Scott and Barrett, 2013). Critical realists see the world as an 'open' and 'emergent', rather than an experimentally closed, system (Zachariadis,

Scott and Barrett, 2013). It is believed that within an 'open system', which is complex, various, and continuously changing, the variable interaction of mechanisms and tendencies prevent constant event conjunctions from occurring (Zachariadis, Scott and Barrett, 2013). This does not mean that causality is not being evidenced or that events are not frequently patterned, but it does mean that from a critical realist perspective, predictions and empirical generalisation are inappropriate in social research (Lipscomb, 2010). Thus, critical realist research relates to 'demi-regularities' that are defined as the partial event regularities that indicate 'the occasional, but less universal, actualisation of a mechanism or tendency, over a definite region of time-space' (Lawson, 1997, p.204). In consequence, causal laws in open systems are considered as non-deterministic and normic, and for critical realists, refer to potentialities rather than certainties (Lipscomb, 2010).

The logic of inference that is adopted by critical realists, retrodution, is valorised as a key element in the critical realist research process (Bhaskar, 1975). Retrodution allows researchers to move from the level of observation and lived experience to the creation of explanation of the underlying structures and mechanisms that account for the phenomena of interest (Zachariadis, Scott and Barrett, 2013). Thus, critical realist research moves from surface appearances to consider underlying structures and processes that may result in mechanisms that might account for that appearance (Wainwright and Forbes, 2000).

Thus,

'For critical realists, the ultimate goal of research is not to identify generalisable laws (positivism) or to identify the lived experience or beliefs of social actors (interpretivism); it is to develop deeper levels of explanation and understanding' (McEvoy and Richards, 2006, p. 69).

In line with pragmatism (a neutral philosophical partner for mixed method research) critical realists do not commit to a single type of research (Johnson and Onwuegbuzie, 2004). They argue that the choice of methods should be dictated by the nature of the research aims under consideration (McEvoy and Richards, 2006). Critical realists accept that qualitative and quantitative research methods have complementary strengths and limitations (Sayer, 2000). Therefore, it is argued that combining qualitative and quantitative methods in a mixed method research design can produce robust meta-inferences that would be difficult to produce using purist methods (Zachariadis, Scott and Barrett, 2013). From a critical realist perspective, the strengths of quantitative methods are the development of reliable descriptions, the provision of accurate comparisons, and the identification of patterns and associations that may

otherwise be masked (McEvoy and Richards, 2006). However, it is believed that correlations between variables alone cannot uncover evidence on causal mechanisms that may generate the observable phenomena of interest (Zachariadis, Scott and Barrett, 2013). In a critical realist approach, these limitations of quantitative methods can be compensated by the use of qualitative methods. From a critical realist perspective, qualitative methods are ‘epistemologically valid’ (Tsoukas, 1989). Their key strength is that they are open-ended and therefore more capable of exploring experiences, perceptions, motivations, contextual factors, and mechanisms that may serve as causal explanations (Bhaskar, 1989). Furthermore, qualitative methods may help to uncover complex concepts and relationships that are unlikely to be captured by standardised quantitative measures (McEvoy and Richards, 2006). Despite of this, the logic of retrodution includes the combination of quantitative and qualitative data, and thus suggests the recognition of mixed methods research (Zachariadis, Scott and Barrett, 2013). Hence, critical realists support a critical methodological pluralism (i.e. mixed methods research), which is grounded in their ontological and epistemological assumptions.

Critical realism could be criticised because Bhaskar applies a theory to the social world that was originally developed for the natural world (Pawson and Tilley, 1997). It is generally accepted that there are structures and mechanisms in the natural world that exist independently of our observation or thoughts about it, for example magnetism (Porter and Ryan, 1996). However, the most important difference between social structures and natural structures is, that the former is not independent of individuals but rather influenced and transformed by the actions of individuals who are a part of the system (Porter and Ryan, 1996). Therefore, Bhaskar’s assertion that there is an objective and independent reality (the real domain) of the social world may be criticised.

Discussion of the critical realist paradigm in relation to the present study

As previously discussed, critical realists see the world as an open system that is complex, various, and continuously changing. Therefore, critical realism takes the complexity of the ‘real world’ into account in which SP is implemented. The stratified ontological perspective of critical realism is in line with assumptions of how complex public health interventions, such as SP, may function (Moore *et al.*, 2014). Critical realists assume that structures and processes result in generative mechanisms that determine change at the level of observable events, behaviours, or phenomena (Zachariadis, Scott and Barrett, 2013). Thus, building relationships with navigators and engagement with services in the third sector may result in generative mechanisms, such as increased self-confidence, motivation, and control over health, which in turn may trigger behaviour change in service uses (e.g. increased physical activity) at an observable level. Moreover, critical realists believe that observable phenomena

are embedded in a wide range of mechanisms, processes, and structures. Thus, the involvement of contextual factors in knowledge generation is key in critical realist research (Zachariadis, Scott and Barrett, 2013). Contrary to positivists, critical realists do not restrict reality to structures, processes, and mechanisms that are visible and empirically observable. Therefore, social structures, mechanisms (e.g. emotions), and experiences and perceptions of stakeholders are given ontological veracity. Thus, critical realism provides a strong philosophical ground for the qualitative research (Objective 2,3, and 4) of this study.

Critical realists agree with authors who argue that the complexity of the social world cannot be captured when phenomena is reduced to correlations between variables (Pawson and Tilley, 1997; Wainwright and Forbes, 2000). Thus, critical realist argue that a pure positivist approach to research, i.e. correlations between SP and pre-defined outcomes, cannot uncover the unanticipated outcomes for service users and the mechanisms that may generate the observable outcomes and provides a superficial picture of complex interventions such as SP (McEvoy and Richards, 2006; Connelly, 2007; Zachariadis, Scott and Barrett, 2013). However, critical realists do not deny the existence of frequent patterns and associations between events, which the present study aims to assess quantitatively alongside the qualitatively reported outcomes from service users (Objective 4). In fact, critical realism promotes the use of quantitative methods to develop reliable descriptions, the provision of accurate comparisons, and the identification of patterns and associations that may be unnoticed using qualitative methods alone (McEvoy and Richards, 2006). However, it does contend the establishment of laws, predictions, and generalisations of results in social research, which are main features of positivist research. The present study is based on the assumption that the implementation of SP, patient uptake and adherence, and service user outcomes are embedded in wider structures, processes, and contextual factors that change over time and across settings. Consequently, it is assumed that outcomes related to SP are likely to differ across settings and timeframes, and what works well in one population may not work in different circumstances or different populations (Husk *et al.*, 2016). Thus, the quantitative research of this study (Objective 4) is in line with the critical realist approach to research, as it does not aim to establish a universal truth or general law, but to understand the quantitative associations between mental wellbeing, energy expenditure and participation in the Luton SP model.

As critical realists recognise the importance of both qualitative and quantitative research, critical realism provides an appropriate philosophical underpinning for the mixed methods systematic review, too (Objective 1).

As this study aims to move beyond the level of observations (positivist approach) and lived experience (interpretive approach) to additionally understand factors shaping implementation, uptake, adherence, and outcomes, retroduction offers a sound logic of inference for the present study. Furthermore, as retroduction suggests a mixed method research design, it is line with the approach of the present study to combine implementation with outcome evaluations, and hence move beyond the rhetoric of quantitative versus qualitative methods (Moore *et al.*, 2014). The underpinning methodological pluralism of critical realism allows researchers, policy makers, and practitioners to understand not only the impact of SP on service users, but also to explore the context in which the observed events were produced (Zachariadis, Scott and Barrett, 2013).

5.4 Using a mixed methods research design

Mixed methods research is defined as research that mixes or combines qualitative and quantitative research methods into a single study (Johnson and Onwuegbuzie, 2004). A mixed methods study design is the most appropriate to meet the aim and objectives of the present study and is supported by critical realism, the philosophical stance underpinning this research study (McEvoy and Richards, 2006; Zachariadis, Scott and Barrett, 2013). Mixed methods research is an expansive and creative form of research allowing the use of multiple methods and approaches to answer different research questions, rather than restricting researchers' choices to specific methods (Johnson and Onwuegbuzie, 2004). It is considered as a complement to traditional qualitative and quantitative research, and therefore is a research method that moves past the previously discussed paradigm war (Johnson and Onwuegbuzie, 2004).

Mixed methods research allows the triangulation of quantitative and qualitative outcome data (Objective 4) to develop a more comprehensive and detailed picture of service user outcomes than could be obtained from single method studies (McEvoy and Richards, 2006). Qualitative and quantitative data can be triangulated additionally for the purpose of confirmation to enhance the reliability and validity of research findings (McEvoy and Richards, 2006; Casey and Murphy, 2009). Confirmation of findings involves the examination and comparison of qualitative and quantitative data to explore the extent to which findings converge or are confirmed (Casey and Murphy, 2009). If the findings of data collected through different methods are consistent, the credibility and robustness of conclusions may increase compared to single method studies (McEvoy and Richards, 2006; Casey and Murphy, 2009). If not, discrepant findings can stimulate further discussion about methodological differences, limitations, and may lead to different conclusions than studies relying on one method alone (Moffatt *et al.*, 2006). Lastly, the quantitative data (service user outcomes) (Objective 4) and

qualitative data (facilitators and barriers to implementation, factors affecting uptake and adherence, and service user outcomes) (Objective 2, 3, and 4) provide a platform for making retroductive inferences about mechanisms, contextual factors, and social structures that may have caused the quantitatively observed impact (McEvoy and Richards, 2006). A critical realist approach is compatible with the three purposes of methodological triangulation, namely completeness, confirmation, and retroduction (McEvoy and Richards, 2006).

Researchers must understand the strengths and weaknesses of quantitative and qualitative research methods in order to use what Johnson and Turner (2003) call the fundamental principle of mixed methods research. According to this principle, researchers should use quantitative and qualitative approaches, strategies, and methods so that the use of mixed methods results in complementary strengths and non-overlapping weaknesses (Johnson and Onwuegbuzie, 2004). Effective use of this key principle is likely to produce findings superior to single method studies and to enhance the integrity of research findings (Creswell and Clark, 2011).

5.4.1 A convergent parallel mixed methods research design

The convergent parallel mixed methods design is used in the present study (Figure 8) as it best matches the aim and objectives of the study and previously discussed reasons for mixing methods (Creswell and Clark, 2011). The convergent parallel design has three main features. Firstly, quantitative and qualitative data collection and analysis are kept separate (Creswell and Clark, 2011). Thus, the level of interaction between the two strands in the study is independent, as the researcher only mixes the two strands when comparing, relating, and interpreting the data and drawing conclusions (Creswell and Clark, 2011). The second feature is that both strands are implemented during a single phase of the research study and results from the two sets of data are used at the same time to compare, relate, and interpret data (Creswell and Clark, 2011). Lastly, the methods have an equal priority within the design, hence they are equally important for addressing the research objectives (Creswell and Clark, 2011).

Specifically, the design for this study includes a systematic literature review and qualitative primary studies to explore (i) factors that hinder and facilitate implementation of SP, (ii) factors that affect uptake and adherence to SP, and (iii) outcomes for service users, to be qualitatively analysed (see Figure 8). Moreover, it includes a quantitative service user outcome analysis (focusing on mental wellbeing and energy expenditure) based on routinely collected secondary data.

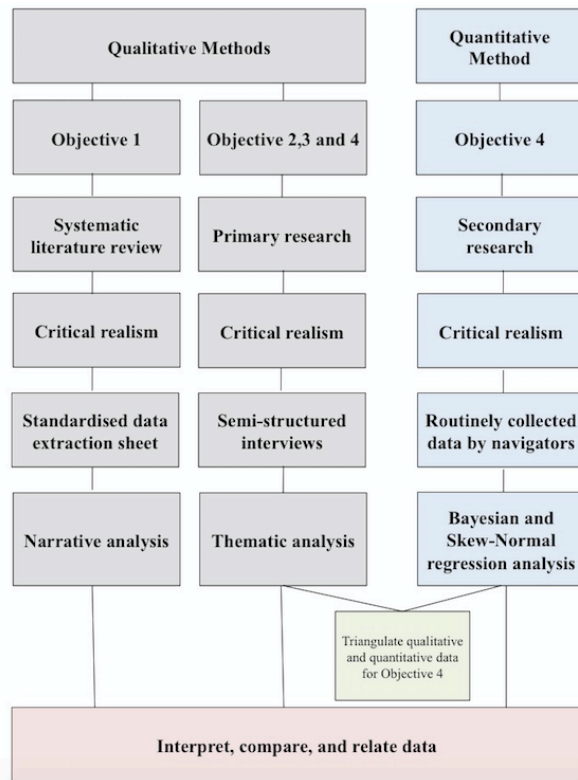


Figure 8: Outline of the convergent parallel mixed methods design used in the present study

5.5 Chapter summary

This chapter critically discussed the positivist, interpretivist, and critical realist paradigms in relation to this study and then explained why the paradigm of critical realism is the most suited approach to this study. In line with the critical realist paradigm, the use of mixed methods was highlighted as the preferred methods (rather than a mono-method) to address the objectives of this study. Lastly, section 5.4 provided a rationale for utilising a mixed methods approach, and a visual representation of the applied convergent parallel mixed methods design for the current study. The design uses three methods: systematic literature review, semi-structured interviews, and an uncontrolled before and after study (cohort design), using secondary data. The findings and results will be merged to provide triangulation and to compare and relate the findings. The following chapter presents the research methods.

6 Chapter 6: Research methods

6.1 Introduction

This chapter presents the research methods used in this study. The objectives use the following different methods: Objective 1 uses a systematic review (section 6.2), objective 2, 3, and 4 qualitative methods (section 6.3), and objective 4 quantitative methods (section 6.4). The chapter ends with a discussion of the ethical considerations in research.

6.2 Systematic review

A systematic review attempts to collate all available evidence that fits pre-specified eligibility criteria in order to answer a specific research question (Higgins and Green, 2008). The findings of systematic reviews can contribute to the growing pool of knowledge and support the decision-making of policy-makers and practitioners (Stewart, 2014). In addition, systematic reviews can inform researchers about the available evidence base, and hence prevent the duplication of existing work, the quality of the available evidence, as well as existing gaps in the literature (Stewart, 2014). In order to understand the existing evidence base on the implementation and service user outcomes of SP in the UK, including the quality of the available evidence, a systematic review was conducted in this study (Objective 1). As discussed in Chapter 5 of the thesis, the systematic review was underpinned by a critical realist philosophy, which is the philosophical stance underpinning this study. Thus, this systematic review aims to go beyond merely reporting facilitators, barriers, and service user outcomes and includes the reporting of mechanisms and contextual factors, which could trigger or produce observed events (see section 5.3.4 for a detailed description of critical realism) (McEvoy and Richards, 2006; Zachariadis, Scott and Barrett, 2013). It is important to highlight that the current systematic review is not to be confused with a ‘realist review’, which is a distinct method based on Pawson and Tilley’s Context-Mechanism-Outcome based ‘realist evaluation’ (De Souza, 2015; Edgley *et al.*, 2016). In a realist review, the identified studies are placed in the domain of *empirical* observations, which give testimony to *actual* events that have been generated by *real* mechanisms. The underlying aim of realist reviews is to search for and identify *real* mechanisms (i.e. causal powers) which result in *actual* events when activated (Edgley *et al.*, 2016). This aim is different to the aim of the current systematic review, which is (i) to collate all available evidence to understand the scope and quality of the evidence base on the implementation and service user outcomes of SP in the UK, and (ii) to reach a deeper understanding of SP, how it can be implemented, and how/why it works or does not work.

6.2.1 Types of studies included in the systematic review

The interest in the concomitant review of qualitative, quantitative, and mixed methods studies, known as mixed studies review (MSR), is increasing, particularly in health sciences (Pluye *et al.*, 2009). MSR can address complex questions comprising qualitative and quantitative aspects related to the implementation and outcomes of health interventions (Pluye *et al.*, 2009; Pace *et al.*, 2012). Hence, this form of literature review has the potential to provide a comprehensive view and a practical understanding of the implementation and service user outcomes of complex health interventions such as SP (Objective 1) (Pace *et al.*, 2012). Therefore, relevant qualitative, quantitative, and mixed methods studies, of all study designs, were included in the systematic review.

6.2.2 Types of participants included in the systematic review

Eligible participants include:

- All stakeholders involved in the implementation and delivery of SP e.g. CCGs, health professionals, navigators, and project managers
- Primary care patients referred to SP

6.2.3 Types of interventions included in the systematic review

This systematic review includes SP interventions based in general practice and involving a navigator. In this referral model, general practice staff (including medical and non-medical staff) refers a patient to a navigator. The navigator's role is to assess the psychosocial needs of the service users, in order to refer them to appropriate sources of support in the third sector. Any referred activities and services were eligible for inclusion. SP programmes, in which the prescribed services are not free of charge for service users for the duration of the programme, are excluded from this review.

6.2.4 Setting of interventions included in the systematic review

Interventions that were implemented in the UK are included in the review. Those interventions that were implemented outside of the UK were excluded.

6.2.5 Outcomes included in the systematic review

To be included in the review, studies had to report at least one of the following outcome measures:

Primary outcomes

The primary outcomes of interest were factors that facilitate and hinder the implementation of SP programmes. Based on the RMIC (discussed in Chapter 4) and critical realist paradigm

(discussed in Chapter 5) underpinning this study, it was expected that outcomes are diverse and context-specific. Therefore, it was not possible to produce an exhaustive list of primary outcomes at the outset. However, based on the review of the relevant literature, examples of primary outcomes include: low number of referrals to SP, lack of collaborative working between the primary care team and the navigator, positive attitudes towards SP, and the organisation of information and networking events for service providers from the third sector (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; RAND Europe, 2012).

Secondary outcomes

The secondary outcomes of interest were outcomes of SP for service users, including personal, social, wellbeing, and health related outcomes. Based on the critical realist paradigm (discussed in Chapter 5) the outcomes of SP were expected to be diverse and context specific and, therefore, can be measured in ways that include but are not limited to:

1. Physiological effects (e.g. reduced blood pressure, reduced blood glucose level)
2. Psychological effects (e.g. improved mental wellbeing measured with the Warwick-Edinburgh mental wellbeing scale (WEMWBS) and reduced anxiety and depression measures with the Hospital Anxiety & Depression Scale (HADS))
3. Social effects (e.g. reduced social isolation, establishment of new friendships, belonging, and group cohesion)
4. Behaviour related effects (e.g. increased self-efficacy measured with the General self-efficacy (GSE) scale and increased levels of physical activity measured with the International Physical Activity Questionnaire (IPAQ))

6.2.6 Search methods for the identification of studies

As SP is a relatively new field in the health and social care sectors, limited numbers of studies are available in peer reviewed articles (Pilkington, Loef and Polley, 2017). Many existing evaluations of local SP interventions are available from informal sources (websites and related web-based information) (Pilkington, Loef and Polley, 2017). Therefore this review used a wide and diverse search strategy, including electronic databases and grey literature searching, as well as the screening of reference lists of relevant studies and reports on SP. The search was limited to literature written in English. No date restrictions were applied. An initial set of searches was conducted in June and July 2016. The aforementioned searches were updated in June and July 2018.

Several articles and evaluation reports of SP programmes in the UK were identified through an initial exploratory online search using the search engine ‘Google’ and the electronic

database ‘Web of Science’. Attending the steering group meetings of the Luton SP team and reviewing the search strategies of relevant literature reviews, helped me to get familiar with relevant terms in this research field (Thomson, Camic and Chatterjee, 2015). The literature review and discussions with experts in the field informed the terms of the search strategy and supported the development of an inclusive and rigorous search strategy for this study. The full search strategy is presented in Appendix 1.

Electronic searches

The following electronic databases were searched, using the full search strategy outlined in Appendix 1:

- The Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Applied Social Sciences Index & Abstracts (ASSIA)
- British Nursing Index
- Web of Science
- Cochrane library
- Medline
- PsychInfo
- SocIndex
- Sport Discuss
- Health Management Information Consortium (HMIC)
- University of York Centre for Reviews and Dissemination (specifically DARE, NHS EED, HTA)

To identify relevant evaluations in UK settings, the websites of the following organisations were searched:

- The Kings Fund
- The Health Foundation
- NESTA
- NICE
- Nuffield Trust
- Department of Health

Additionally, the grey literature was searched in OpenGrey, Google, and Google Scholar. The search for grey literature was based on the combination and iterative modification of the search terms ‘social prescribing’, ‘social prescription’, ‘primary care’, ‘community’ and

‘referral’, which were identified as the most relevant terms in the exploratory and database search. In addition, reference lists of all relevant studies, reviews, and reports were searched.

6.2.7 Selection of studies

After eliminating the duplicates (studies that were identified more than once by the search engines), an initial screening of titles, abstracts, and summaries (if applicable) was undertaken to exclude records that clearly did not meet the inclusion criteria. Each record was classified as ‘include’ or ‘exclude’ to identify relevant and exclude irrelevant literature. An inclusive approach was taken at this stage and, if I was uncertain about the relevance of a publication or report, it was left in. The full text was obtained for all the records potentially meeting the inclusion criteria (based on the screening of titles and abstracts/summaries only). If not available through electronic databases, the British Library and University libraries were used to obtain the full text of articles to determine the eligibility of all potentially relevant studies. In a second step, all the full text papers were screened against the inclusion criteria, using a standardised tool developed for this study. Studies that did not meet the inclusion criteria were listed with the reasons for exclusion. Multiple publications and reports on the same SP programme were linked together and compared for completeness. The paper/report containing the most complete data on the SP programme was identified as the primary article and included in the review, which was usually the original study or most recent evaluation report. An adapted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) flow chart was used to summarise the study selection process (Moher *et al.*, 2009a).

6.2.8 Data extraction and management

A data extraction sheet was developed which was tailored to the requirements of the review. The data extraction sheet was tested on three included papers to ensure it can be reliably interpreted and can capture all relevant data from different study designs. Extracted data included authors, year of study/report, type of paper (e.g. journal article, annual evaluation report), study design, description of the SP programme (model descriptions, referrers, target group, geographical area), study sample, factors that facilitated the implementation, factors that hindered the implementation, and service user outcomes. Data for analysis were extracted from the included studies, using the standardised data extraction sheet, and managed in an Excel spread sheet.

6.2.9 Data synthesis

All findings from included studies were synthesised narratively. Narrative synthesis relies primarily on the use of words and text to present the findings of studies (Popay *et al.*, 2006). A wide range of factors that hinder and facilitate the implementation of SP and service user

outcomes were identified by the systematic review. Service user outcomes were assessed using different qualitative and quantitative study designs, as well as different quantitative tools, and statistical methods. Appendix 2 presents the 24 different tools used by included quantitative studies to assess service user outcomes. The majority of quantitative tools (N=18) were used by one study only (see Appendix 2) and therefore the results could not be compared between studies. Given this significant heterogeneity, quantitative pooling (i.e., statistical meta-analysis), was not a feasible method to synthesise service user outcomes in this review (Popay *et al.*, 2006; Lewis *et al.*, 2017). In addition, due to small sample sizes and incomplete data, studies using the same study design and outcome measure (e.g. the 14-item WEMWBS) only described data trends (see Appendix 2) preventing a statistical (meta-analytic) summary (Lewis *et al.*, 2017). The ‘Guidance on the Conduct of Narrative Synthesis in Systematic Reviews’ by Popay *et al.* and the guidance of the Cochrane Consumer and Communication Review Group were used to advise the narrative synthesis in this study (Ryan, 2013).

The first stage of the synthesis was to become familiar with the included studies/reports and their findings. As this review included studies of diverse designs, methodologies, and SP programmes, each included record was described separately, summarising the same features (Popay *et al.*, 2006; Ryan, 2013). These summaries were structured such that they provide details of the setting, intervention, study design, participants, and methods. The relevant findings and results of each study/report were systematically and comprehensively reviewed. Any important characteristics of studies, relationships between data, patterns in data, and differences and similarities between findings/results were written down at this stage (Popay *et al.*, 2006; Ryan, 2013).

In a second step, extracted data were reviewed to develop themes across included records, hence an inductive approach was taken in which themes derived from the data rather than pre-existing theory or the literature (Braun and Clarke, 2006). As factors that hinder and facilitate the implementation of SP interventions (primary outcomes) were diverse, a wide range of themes was developed across the records. For the service user outcomes (secondary outcomes), most of the data could be divided in few themes. As the themes appeared to be rather brought, sub-themes were developed to structure the data in more detail. The inductively derived themes and sub-themes were reviewed and refined throughout the synthesis process (Popay *et al.*, 2006). Therefore, there was a continuous back and forward movement between the outlined steps, i.e. the data synthesis process was cyclic rather than linear.

In a third step, the extracted data was matched to the developed themes and sub-themes (Popay *et al.*, 2006). As a deeper understanding of the data, as well as the relationship between the data, developed, the themes and sub-themes were further refined or discarded. This process continued until the themes, sub-themes, and data formed a coherent pattern.

Finally, in line with the objectives of the systematic review, factors that hinder and facilitate the implementation of SP interventions, as well as service user outcomes were presented by the developed themes and sub-themes. In line with the critical realist paradigm, relationships between reported facilitators, barriers, service user outcomes, and contextual factors were acknowledged in the findings when appropriate. In addition, if reported, the mechanisms that may have triggered the observed outcomes were considered in the analysis, too.

6.2.10 Assessment of methodological quality

SP is an emerging field of research. The majority of evidence is available from unpublished evaluation reports, often of poor methodological quality (Centre for Reviews and Dissemination, 2015; Kinsella, 2015; Thomson, Camic and Chatterjee, 2015). To capture available evidence on the implementation and service user outcomes, for which more rigorous studies are lacking, this review did not exclude records on grounds of methodological quality. Instead, the limitations of poor quality records were made explicit to differentiate between more and less robust studies. This allowed the interpretation of findings in relation to the quality of included studies and informed future research.

To appraise the methodological quality of included studies, the Mixed Methods Appraisal Tool Version 2011 (MMAT-V 2011) was used (Pluye *et al.*, 2011). The criteria for the initial MMAT were based on a review of 17 health related systematic mixed studies reviews (Pluye *et al.*, 2009). The criteria for the current version (MMAT-V 2011) were further informed by methodological experts, workshops with national and international researchers, and efficiency and reliability tests of the pilot MMAT (Pace *et al.*, 2012; Queiroga *et al.*, 2015). The full MMAT-V 2011 criteria are presented in Appendix 3.

This systematic review was registered in the international prospective register of systematic reviews (PROSPERO) (CRD42017079664).

6.3 Qualitative methods

Qualitative methods were used to explore the implementation of SP in Luton (Objective 2), factors affecting patient uptake and adherence to SP (Objective 3), and service user outcomes (Objective 4).

6.3.1 Sample selection

Sampling strategies in qualitative research are typically based on non-probability sampling methods, in which participants are chosen through non-random methods for inclusion into a research study (Kandola *et al.*, 2014). Purposive sampling is a method of non-probability sampling, in which participants are selected based on certain predefined criteria, such as experiences or knowledge (Saks and Allsop, 2007). Purposive sampling is often used when small samples are studied using focused data collection methods such as semi-structured interviews (Curtis *et al.*, 2000). Furthermore, purposive sampling ensures that representation from the population of interest is achieved (Lakhanpaul *et al.*, 2014). In this study, purposive sampling was employed to select stakeholders involved in the implementation and delivery of SP, as well as service users. For objective 2, stakeholders involved in the implementation of the Luton SP programme (GPs, navigators, service providers in the third sector, and managers/decision-makers) were included in the study. For objective 3, stakeholders involved in the delivery of the Luton SP programme (GPs, and navigators) and service users were included. For objective 4, service users only were included.

Stakeholders involved in the implementation and delivery of the Luton social prescribing programme

The RMIC (see Chapter 4) clarifies that the implementation and operation of SP requires the integration of multiple stakeholder groups at several levels (Angus and Valentijn, 2018). Thus, this study aimed to explore the perspectives of multiple stakeholder groups to understand the implementation of SP and factors affecting patient uptake and adherence. Therefore, the views of the following four key stakeholder groups involved in the implementation and delivery of SP were sought:

- GPs
- Navigators
- Managers and decision-makers
- Service providers in the third sector

Given the relatively small size of the Luton SP programme, it was planned to interview all navigators, managers and decision-makers, and at least one GP per participating surgery, for this study. At the planning stage, 35 service providers in the third sector were accredited by the Luton SP programme and 15 did receive referrals from navigators. Also, a number of service providers considered completing the accreditation process to be part of the Luton SP programme. It was planned to interview five to eight service providers in the third sector.

Thus, based on the number of stakeholders involved in the SP pilot programme in Luton, it was planned to interview 22 to 25 stakeholders involved in the implementation and delivery of the Luton SP programme. Applying the purposive sampling strategy, the following stakeholders were selected for interviews:

GPs, one from each participating surgery (stakeholder group 1):

- General practice 1 (1)
- General practice 2 (1)
- General practice 3 (1)
- General practice 4 (1)

Navigators (stakeholder group 2)

- Navigator 1
- Navigator 2
- Navigator 3
- Navigator 4
- Navigator 5

Managers and decision-makers (stakeholder group 3):

- Better Together Project Manager (1)
- Community Development Manager taking SP business lead (1)
- Social Prescription Project Manager (1)
- Luton CCG members involved in the implementation of SP (2)
- Steering group members and key partners from the third sector (2)
- Commissioner (1)
- External consultant (1)

Service providers in the third sector (stakeholder group 4):

The purposive sampling strategy was used to choose a diverse sample of five to eight service provider organisations to represent multiple service provider perspectives. Service providers in the third sector were selected based on the following criteria:

- Stage of accreditation process
- Offered activities (e.g. physical activity, social, or creative)
- Number of employees
- Commissioning status

Service users of the Luton SP programme

Previous studies assessing SP services included service users who are participating in SP at the time of the study or those who completed the SP service as intended (White and Salamon, 2010; Friedli, Themessl-huber and Butchart, 2012; Dayson and Bashir, 2014; Kimberlee *et al.*, 2014; The Health Foundation, 2015). Excluding those service users who were referred to SP but partially, or not at all, engaged with the service may introduce selection bias in existing studies, as the samples do not represent the experiences and perceptions of the service users who dropped out or partly engaged with the service (Wolke *et al.*, 2009). To reduce selection bias and to develop a comprehensive understanding of (i) factors affecting uptake and adherence (Objective 3) and (ii) outcomes for service users (Objective 4), across all engagement levels, this study included all patients that were referred to the SP service in Luton by a GP, independent of their engagement levels. This is in line with the epistemological perspective of critical realist researchers of not ignoring uniqueness and complexities of individuals and subgroups (in this case different engagement levels in the SP programme) (Zachariadis, Scott and Barrett, 2013).

To reduce recall bias, service users had to be referred to the SP service sometime over the past 12 months from the start of the recruitment period. Furthermore, service users needed to have sufficient English language skills to understand and answer the interview questions in order to be included in the study. As interviews were used to collect rich data, service users with significant hearing impairments were excluded from the study. The inclusion and exclusion criteria for service users are summarised in Table 2.

Table 2: Inclusion and exclusion criteria for the service user sample

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">• Referred to SP over the past year (from the point following the start of recruitment of participants in the study)• Sufficient English speaking skills	<ul style="list-style-type: none">• Service users with significant hearing impairments

It would have been beneficial to include patients who refused to be referred to the SP programme during a consultation with a GP, to understand factors affecting non-uptake from a patient's perspective. As GPs did not reported those patients who refused to be referred to SP, this was not possible in the current study. However, to reduce this limitation, some data on the reasons for non-uptake of the SP programme were collected from the GP perspective.

In previous studies, the number of patients and service users who were interviewed to explore their experiences with health services ranged from nine to 28 (Ralston *et al.*, 2004; Brown *et al.*, 2006; Greenfield *et al.*, 2014). Previous studies that aimed to explore the experiences and perceptions of service users with SP, conducted interviews with 15 to 17 service users (White, 2012; Dayson and Bashir, 2014). Baum (2002) suggests that a sample size between 12 to 20 individuals is suitable for research that seeks to understand a phenomenon from a specific stakeholder perspective. Based on the practice of previous studies and the suggested sample size by Baum (2002), the planned sample size was between 15 and 20 service users for this study.

6.3.2 Recruitment

Methods of recruiting participants to this study varied across stakeholder groups. For this reason, the approaches undertaken to recruit different stakeholder groups will be discussed separately in the following section.

Recruitment of navigators and managers and decision-makers

The recruitment period for navigators and managers/decision-makers was between November 2016 and April 2017. Managers, decision-makers, and navigators were invited to the study via email. I had access to the email addresses of these relevant stakeholders through previous correspondence or the list of invitees to previous meetings. The invitation email contained: an invitation letter (Appendix 4), an information sheet (Appendix 5), and a contact sheet (Appendix 6). Potential participants were asked to send back the contact sheet via email within 5 working days, indicating whether they wish to participate in the study, and if so, their preferred way of contact to arrange an appointment.

Recruitment of GPs

The recruitment period for GPs was also between November 2016 and March 2017. Navigators, the project manager, and members of the Luton CCG supported the recruitment of GPs involved in the Luton SP programme for this study. The ways of recruiting GPs was dependent on their relationship with members of the SP team, their colleagues, and practicalities. One way to recruit GPs was to ask the navigators for help, as they built relationships with most involved GPs. The navigators introduced me to three leading GPs a couple of weeks before the recruitment period of this study, so that I could introduce myself in person, explain the research study, and make GPs aware about it in advance. I also encouraged GPs to discuss this study with their colleagues, in order to create awareness about the study among involved GPs. Once the recruitment period started, the navigators invited involved GPs to an interview via email, in which I was copied in. The study information sheet

(Appendix 5) and contact form (Appendix 6) was attached to this email. Navigators asked GPs to contact myself if they were interested in participating in an interview. Another way to recruit GPs was through the project manager. The project manager informed GPs about the study before the recruitment period during routine meetings. Once the recruitment period started, the project manager emailed three lead GPs and asked them to contact me via email if they were interested in participating in the study. The study information sheet (Appendix 5) and contact form (Appendix 6) was attached to this email. The third way to recruit GPs was through the Luton CCG. I worked closely with members of the CCG from the early planning phase of my study, which allowed me to build good relationships with members of the CCG and ensure awareness of my research study. Two CCG members sent emails to all practice managers (N=4) and lead GPs (N=8) participating in the SP service in Luton to invite GPs to participate in the research study. Two emails were sent as reminders. The study information sheet (Appendix 5) and contact form (Appendix 6) was attached to these email. The forth way to recruit GPs was through the help of GPs who participated in the interview themselves. At the end of the interview, I asked GPs if they knew of any other GPs involved in SP who could participate in my study and what the best way would be to contact them. Following this question, one GP emailed another GP immediately after the interview to invite him to participate in the study. GPs also told me that they would talk to other GPs and that they would share their experience of participating in the interview in the next practice meetings to encourage other GPs to participate.

When a GP replied to any of the relevant emails and was willing to participate in the study, based on their preferences, I either called or emailed GPs directly to arrange an appointment for the interview. Another option that one GP asked for was to arrange an appointment with the receptionist via the phone. Challenges associated with recruiting healthcare professionals for research studies were noted in previous research (Popay *et al.*, 2007a; Cook, Dickinson and Eccles, 2009). In this study, the recruitment strategy for GPs was designed in a way that one GP would have heard about the study at different time points and through different means, to increase response rates. For example, I introduced myself to a GP at some point to create awareness about the study. Then few weeks later the navigator would have sent an email to invite GPs to the study, which would have been followed up by another email from the Luton CCG.

Challenges of recruiting GPs

Besides the various routes to recruit GPs and reminders sent to GPs and practice managers, the response rate from GPs was very low. Due to structural changes in the NHS, one participating surgery was closed at the beginning of the recruitment period of this study. The

closure of this surgery required the transfer of patients to another participating surgery. Besides several attempts and reminders, all GPs working in general practice 2 refused to participate in the study, due to the increased workload of registering and assessing new patients.

Recruitment of service providers in the third sector

The recruitment period for service providers was between November 2016 and March 2017. Two service providers in the third sector were key partners and members of the steering group and I established good relationships with them during the early stages of the study. These two providers were recruited via email, to which the recruitment pack consisting of an information sheet (Appendix 5) and contact form (Appendix 6) was attached. Navigators and the project manager were asked for help to recruit other service providers. I reviewed the list of all accredited service providers to select potential participating organisations based on their size, offered activities, and commissioning status. In addition, I received information about the characteristics of third sector organisations which considered to get involved with SP but did not start the accreditation process at the time the recruitment period started. The project manager and navigators contacted the selected providers via phone or email to inform them about the study and to ask them whether they were willing to participate in an interview. If so, I contacted the service providers via phone to arrange an appointment for the interview. If they had not received the information sheet already (Appendix 5), I sent it to the contacted service providers via email to make sure they understand their rights and the purpose of the study.

Recruitment of service users

The recruitment period for service users was between February 2017 and October 2017. Navigators acted as gatekeepers to protect the personal information and privacy of service users. Two different methods were used for recruitment. For the first method, navigators were asked to identify eligible service users from the records, using the inclusion and exclusion criteria (Table 2). Then navigators sent out a recruitment pack, on behalf of the researcher, to the identified eligible service users. The recruitment pack consisted of an invitation letter (Appendix 7), an information sheet (Appendix 8), a contact sheet (Appendix 9), and a pre-paid envelope.

The other method to recruit service users was that navigators identified eligible service users during routine appointments and handed out the recruitment packs (identical to the ones sent out by mail) at the end of them. To support navigators and to ensure that consistent information was provided to service users, guidelines for handing out the recruitment packs to

eligible service users were developed (Appendix 10). All the information in the guidelines for navigators was also clearly stated in the invitation letter and information sheet of the recruitment pack. Therefore, there was no difference in provided information between service users who received the recruitment pack via mail and those who received it from the navigator after a routine appointment.

Sending and handing out the recruitment pack meant that service users had time to read and consider the information about the study in their leisure time at home. If service users agreed to take part in the study, they could either use the pre-paid envelope to send the contact sheet back to the researcher, or alternatively bring it back to the reception in the general practice for the researcher to collect. Potential participants were asked to return the contact sheet within 14 days if they wished to participate in the research study. Once the researcher received the returned contact sheet, service users were directly contacted to arrange a meeting for a one-hour interview. Service users were contacted based on their preferred time and method of contact (phone, email), as stated in the contact sheet.

In total, 30 recruitment packs were sent out to eligible patients and 16 packs were handed out to eligible service users in routine appointments. 24 service users refused to participate in the study when navigators approached them therefore, no recruitment pack was sent/handed out to those service users.

Challenges of recruiting service users

There were a number of challenges to the recruitment of service users for this study. Firstly, at the beginning of the recruitment period for service users, one of the two employed navigators in the Luton SP programme resigned (February 2017). In order to recruit service users for this study, it was planned that the navigators hand out the recruitment packs to eligible service users during the handover period to the new navigator. However, the new navigator resigned from the role, too, so that the handover period did not take place. Service users were informed about the navigator's resignation via text, so that no opportunity to invite service users to my study arose. Therefore, technically from the beginning, there was only one navigator recruiting service users for this study. Three months into the recruitment period, this navigator resigned from the Luton SP programme (May 2017), too, so that the recruitment of service users was put on hold. Two new navigators who were recruited in April 2017, were willing to support the recruitment of service users for this study, but could not access service user information due to delays in moving into the surgeries. Due to technical challenges to set up a NHS smart card for one navigator, the delivery of SP was further delayed in two practices, which ultimately delayed the recruitment of service users for this

study further. Once both navigators were placed in the surgeries, they primarily focused on settling in their new job roles and building relationships with service users.

6.3.3 Data collection

Ethics approval for the qualitative study was provided by the University of Bedfordshire (Appendix 11) and the NHS Research Ethics Committee (Appendix 12).

Interviews

Typically, qualitative methods are used to provide rich and in-depth information in order to capture the complexity of a phenomenon (Saks and Allsop, 2007; Bowling, 2014). As the objectives of this study were to identify factors that hinder and facilitate the implementation of the Luton SP programme (Objective 2), to explore factors that affect patient uptake and adherence to the Luton SP programme (Objective 3), and service user outcomes from a service user perspective (Objective 4), interviews were considered the most appropriate data collection method to meet these three objectives. This section will outline why individual semi-structured interviews were a suitable technique for collecting information for this study's purpose.

Interviews are the most widely used data collection tool in qualitative health research (Green and Thorogood, 2004; Holloway, 2005). At a basic level, a qualitative interview involves one person asking questions (interviewer), more or less directed by research needs, which another answers (interviewee) (Green and Thorogood, 2004). When conducted for the purpose of research, the information collected is transcribed, which then becomes the data to be analysed.

In the current study context, research participants may know each other, work together, and even depend on each other (e.g. have an employer and employee relationship). The advantage of individually conducted interviews is that there is no group pressure or fear of disclosure, which could bias the study findings. Interviews provide a private environment and give participants the opportunity to describe their experiences and perceptions in detail (Holloway, 2005). Furthermore, they enable the researcher to explore experiences and perceptions in greater detail, probe, and follow up responses (Holloway, 2005).

Interviews as a method of qualitative data collection assume that, by asking the right questions and employing techniques of active listening, probes, and prompts, the researcher can explore the phenomenon under study in detail (Holstein and Gubrium, 2004). However, interviews do not offer direct access to facts or events, instead they study what people say,

hence the information obtained is a respondent's interpretation of a situation (Green and Thorogood, 2004). From a critical realist perspective, interview responses are not thought to reflect reality. Instead, they are considered to represent an incomplete account based on the personal experience and view of a respondent, which is influenced by contextual factors and specific circumstances (Miller and Glassner, 2004).

Interview methods

Interviews are commonly categorised as structured, semi-structured, and unstructured (Holloway, 2005). In a structured interview, the agenda is set by the researcher (Corbin and Morse, 2003). Although structured interviews may generate some qualitative data, they tend to be based on a rigid, unchanging format to generate comparable answers from each respondent (Green and Thorogood, 2004; Holloway, 2005). Structured interviews are typically used as a quantitative data collection tool in survey designs (Holloway, 2005). As the necessary level of standardisation limits the depth of responses, structural interviews would not be an appropriate method to explore and capture the depth and complexity of factors that affect the implementation of SP, patient uptake, and adherence to SP. Furthermore, structured interviews would hinder the identification of unanticipated, but important outcomes from the service user perspective. As this study is based on critical realism, and hence aims to delve beneath the surface of superficial responses to understand phenomena, a structured interview is an inappropriate qualitative data collection tool for this study.

At the other end of the continuum are unstructured interviews. While the definitions of an unstructured interview vary, their agreed characteristics are that the interview is not based on a predefined theoretical framework and questions (Green and Thorogood, 2004; Saks and Allsop, 2007). Thus, although the interviewer may begin by asking a broad question, the interviewee's responses determine the direction and topics of the interview (Moyle, 2002). Unstructured interviews are useful to develop an understanding of little known topics, to understand the interviewees' language, and specific cultural context of the research setting (Bowling, 2014). However, due to the lack of an explicit focus, unstructured interviews are less useful to explore a particular part of a phenomenon in detail, as it is the aim of this study (Bowling, 2014). It is unlikely that the different groups of stakeholders would discuss the implementation and delivery of SP in a sufficiently similar way to identify facilitators and barriers, without an interview guide. An interview guide, also referred to as interview schedule, is a list of predefined topics or open-ended questions that need to be covered during the interview (Green and Thorogood, 2004; Brod, Tesler and Christensen, 2009). Similarly, this applies to factors that affect engagement in SP, and to the outcomes for service users.

Therefore, unstructured interviews were not an appropriate tool to meet the objectives of this study.

The most commonly used interview mode in qualitative health research is between these two extremes, hence semi-structured (Green and Thorogood, 2004; Holloway, 2005). In a semi-structured interview, the researcher typically uses an interview guide (Green and Thorogood, 2004; Brod, Tesler and Christensen, 2009). Thus, like in structured interviews, the researcher determines the structure of the interview through the pre-defined questions asked (Corbin and Morse, 2003). However, unlike in structured interviews, the researcher retains the flexibility to follow up questions through probes for further clarification and interesting lines of inquiry as they arise (Green and Thorogood, 2004; Brod, Tesler and Christensen, 2009). Therefore, the nature of open-ended questions and a certain degree of flexibility allow the researcher to identify and explore unanticipated responses. Another difference to structured interviews is that the participant controls the amount and kinds of information provided in responses and their relative importance (Corbin and Morse, 2003; Green and Thorogood, 2004). Therefore, the interviewer must be flexible to switch direction from the guide while still covering all pre-defined questions during the interview (Brod, Tesler and Christensen, 2009).

In this study, using a pre-defined set of open-ended questions in a semi-structured interview allowed me to focus the interview on the topics of interest whilst still being able to capture the depth and complexity of different stakeholders' experiences and perspectives, and to explore unanticipated findings. Therefore, semi-structured interviews were considered as most appropriate qualitative data collection tools in this study.

Interview modes

Semi-structured interviews can be carried out face-to-face, over the telephone, or via the Internet (e.g. Skype) (Holloway, 2005). The advantages of face-to-face interviews are that researchers have the opportunity to respond to non-verbal, i.e. social and visual cues, for further clarification, probing, and interpretations (Holloway, 2005). Furthermore, it may be easier for the interviewer to establish rapport with the interviewee and to encourage more thoughtful responses (Holloway, 2005; Bowling, 2014). Given that all potential study participants lived or worked in Luton or London at the time the study was conducted, all semi-structured interviews were conducted face-to-face to collect data for this research study.

Informed consent

Written informed consent for the participation in the study, that the interview is audio-recorded, and the use of verbatim anonymised quotes in the PhD thesis, research reports, and

articles was obtained from each participant before commencing with the interview (Appendix 13 and Appendix 14).

Developing the topic guides

In semi-structured interviews, a topic guide is constructed before the first interview (Bowling, 2014). This guide consists of a set of questions in a proposed order (Brod, Tesler and Christensen, 2009). Typically, questions are developed from different sources including the available literature on areas of interest, experience, and expert opinion (Brod, Tesler and Christensen, 2009). This section will outline the steps of the development of the interview guides for the study.

For objective 2, four stakeholder groups (GPs, service providers, navigators, and managers and decision-makers), each with specific roles and experiences, were interviewed. As the experiential knowledge related to the implementation and delivery of the SP service differed between the four stakeholder groups, four different topic guides were developed to explore factors that facilitate and hinder the implementation of the Luton SP programme (Appendix 15-Appendix 18). As navigators and GPs were involved in the delivery of the SP service and closely worked with service users, the interview guides for these two stakeholder groups included questions on factors affecting patient uptake and adherence (Objective 3), too. An additional interview schedule for service users was developed to explore the factors affecting uptake and adherence to SP (Objective 3), as well as the outcomes for service user (Objective 4) from the service user perspective (Appendix 19).

Topic guides for this study were developed in a series of steps. Firstly, the initial interview guides were informed through a review of the existing literature, the pathway of the Luton SP programme (Figure 3) and the objectives of the study. In a second step, researchers who conducted studies in relevant research fields were identified and contacted via email or LinkedIn (a business-oriented online service used for professional networking) to seek information about previously used interview guides. As a novel qualitative researcher, it was useful to compare and learn from the structures of previous interview guides. In a next step, the drafted topic guides were discussed with my supervisors and other experts in the field, via telephone, who provided valuable feedback and shared their experiences of working in this research field. Lastly, all interview guides were piloted with a convenience sample of one to four relevant stakeholders of each of the five groups, in order to test the use of language, clarity, and appropriateness of questions.

The topic guides developed for this study (Appendix 15-Appendix 19) started with an introduction, which explained the rights of the participant, the purpose of the study, the processing and use of information, and allowed time for any questions. After this short introduction informed written consent was obtained (Appendix 13 and Appendix 14). This was followed by ‘warm-up’ questions, which asked participants about themselves, for example about their role in the SP programme, when they joined the programme, or their background. These opening questions were used to establish rapport with the interviewee and to understand their background and role (if applicable) (Robson, 2002). The main body of questions aimed to address the objectives of the study as outlined in Chapter 1, section 1.3. The questions in the interview guides for health professionals, navigators, and service providers were structured around the roles and relevant pathways for each stakeholder group. Hence, questions to health professionals were structured around setting up the programme in a practice, the first part of the SP pathway, i.e. the identification and referral of primary care patients, and their reasons for uptake or non-uptake. Questions for navigators were structured around their experience of performing the navigator role and establishing themselves in a surgery. Questions for service providers were structured around their reasons for engagement, the accreditation process, and final path of the SP programme, i.e. receiving referrals and providing services. As managers and decision-makers were not directly involved in delivering the service, questions for this stakeholder group were structured around the implementation process. By asking a general question, for example *‘What facilitated the implementation process?’*, managers had the opportunity to talk about factors that were relevant from their perspective, determined by their role and responsibilities. In general, the interview guides were designed to support the development of an understanding of facilitators and barriers to the implementation of the SP programme, patient uptake, and adherence.

Similar to the topic guides for health professionals, navigators, and service providers, the interview questions for service users were structured around the Luton SP pathway (Figure 3) from a service user’s perspective. Bertotti *et al.* (2017) divided the SP pathway of the SP programme in City and Hackney in the same three stages as the Luton SP pathway was divided in the interview guides for service users:

- Stage 1: GP referral process
- Stage 2: Interaction and work with SP navigator
- Stage 3: Interaction and work with third sector organisations/ referred activities and services

Going through each stage of the SP pathway from a service user's perspective, supports the development of an understanding of factors affecting the uptake and adherence, as well as experienced outcomes. It provides the opportunity to explore the reasons for a service user's behaviour, decisions, and experiences, by asking, for example, '*Why did you agree to be referred to the social prescription programme?*' (Stage 1) or '*Did you attend the services/activities as agreed with the navigator? Why or why not?*' (Stage 3).

As a closing question, participants were asked whether they would like to tell me anything else I have not asked them about, to give them the opportunity to freely express their thoughts and views. At the end of the interviews, the participants were thanked and given the option to provide me with contact details to which I could send a summary report of the findings or relevant publications. Interviews were planned to last between thirty to sixty minutes.

6.3.4 Data preparation

In this study, each interview was recorded on a digital audio-recorder, transferred onto a password-protected laptop, and then transcribed verbatim as a Microsoft Word document. All transcripts were anonymised, and therefore did not include any identifiable information of participants, such as names or addresses. To ensure that the transcripts were an accurate representation of the interviews, each transcript was compared to the original audio-recording. Then the transcripts were imported into the computer assisted qualitative data analysis programme QSR NVivo 11 to help manage the transcripts and coding the data.

6.3.5 Data analysis

Dey (1993) describes data analysis as a process in which raw data is cut into pieces and then put together in a different form to produce answers to research questions. However, there are different qualitative approaches and no fixed rules on how to conduct qualitative analysis exist (Braun and Clarke, 2006). Braun and Clarke (2006) highlight that it is important that the employed approach is consistent with the methodology of the study, including the philosophical perspective of the researcher, as well as being appropriate for the study objectives. Given that critical realist researchers are interested in contextual factors too, analytical approaches that study lived experiences and ways of expressing talk alone, as for example conversation analysis, are not appropriate for this study.

Thematic analysis is an established method in qualitative research, to identify, analyse, and report patterns within data (Braun and Clarke, 2006). An advantage of thematic analysis is that it is a flexible method that can be applied across a range of theoretical and epistemological approaches (Braun and Clarke, 2006). Thematic analysis can provide a rich,

detailed, and complex account of data that considers contextual factors and looks beyond surface appearance of social processes and lived experience (Braun and Clarke, 2006). In this study, I considered that thematic analysis could produce a detailed account of the data, while taking into account contextual factors, which is in line with the critical realist philosophy and appropriate to achieve the study aims and objectives.

However, there is a range of methods to conduct thematic analysis, and hence no clear agreement and rules exist on how it should be performed (Braun and Clarke, 2006). In this study, the thematic analysis procedure detailed by Braun and Clarke (2006) was used as guidance to analyse the data. The phases of the thematic analysis applied in this study were as follows:

Phase 1: Familiarisation with the data

The process of collecting data and transcribing the audio-recordings of interviews facilitated the beginning of familiarisation with the data. That I listened to all interviews several times and compared them to the transcripts to check for accuracy was helpful to develop a more thorough understanding of the data. During this process, I made notes of ideas, observations, and relationships that seemed to be important in relation to the research objectives.

Phase 2: Generating initial codes

‘Codes’ describe the topics of segments of the raw data (Braun and Clarke, 2006; Sutton and Austin, 2015). After the familiarisation stage, transcripts were systematically read through to produce codes emerging from the data. Hence, in this study, codes were inductively constructed, based on what participants reported in the interviews, and line-by-line coding was used to code the entire data set. Data on apparent ‘deviant cases’, where opinions and experiences were in contradiction with those previously reported, were examined and coded to enhance validity (Barbour, 2001). A computer assisted qualitative data analysis programme, called NVivo version 11, was used to code, i.e. label data segments, store, and organise the data. Using NVivo to code the data was useful as it quickly and efficiently allowed accessing all data across transcripts assigned to one code, which is relevant for later stages of the analysis (generating themes and categories and data synthesis). Furthermore, codes in NVivo can be presented in context, i.e. where they appear in the transcripts, which was useful to clarify codes and to understand their relationship to the data during the analysis process.

Phase 3: Generation of themes and sub-themes

The generation of themes refocuses the analysis at the broader level, which involves sorting the inductively derived codes into sub-themes and themes (Braun and Clarke, 2006; Sutton and Austin, 2015). As some themes appeared to be quite broad, sub-themes were generated to further organise the data under each theme (Braun and Clarke, 2006). Contradictory opinions and experiences related to one theme were presented and interpreted to reflect on various viewpoints of one issue and to enhance validity (Barbour, 2001). Exploring the relationship between codes, sub-themes, and themes was of major importance to organise the inductively derived codes into sub-themes and themes. Those initial codes that did not seem to belong to any of the main themes at this stage of analysis, were temporarily sorted under a theme called 'miscellaneous' (Braun and Clarke, 2006). The NVivo software facilitated the comparison of the data across participants and to retrace where it came from throughout the whole analysis. This is relevant for later stages of the analysis, as it enabled the presentation of outlying cases that did not fit with the central interpretation (Anderson, 2010). Visual representations, i.e. tables in Microsoft Word, were used to organise the inductively produced codes into sub-themes and themes.

Phase 4: Reviewing codes, sub-themes, and themes

During this phase, the set of sub-themes and themes were revised and the codes sorted under the theme miscellaneous were dealt with. Data required further reorganisation, as I gained a deeper understanding of the data, as well as relationships between codes, sub-themes, and themes. Firstly, I read all the codes, sub-themes, and themes again to review whether they appeared to form a coherent pattern. When I identified that the pattern is not coherent, I moved, reworked, or discarded codes, sub-themes, or themes. Then, I re-read the entire data set to ascertain that the themes reflected the meanings of the data and to check that I have not missed relevant data in earlier coding stages. When I identified missing data, I coded it and placed it under an appropriate theme. Thus, the generation, revision, and discarding of codes, sub-themes, and themes was not linear. Instead, there was continual movement back and forwards between them, as deeper understanding of the data developed. Hence, thematic analysis is an on-going and cyclic process (Dey, 1993; Braun and Clarke, 2006; Creswell, 2009).

Phase 5: Data interpretation and presentation

The interpretation of data goes beyond the description of data, i.e. summarising what participants say (Braun and Clarke, 2006; Sutton and Austin, 2015). Keeping with the critical realist approach, I was guided by questions such as 'what conditions are likely to have given rise to an experience?' and 'why do people talk about something in this particular way (as

opposed to other ways)?’ to unravel the surface meanings of data and to explore how contextual factors impinge on peoples’ experiences (Braun and Clarke, 2006).

As thematic analysis was used to synthesis the qualitative data, the qualitative research findings for objectives, two, three, and four were presented by themes. As the identified barriers and facilitators (Objective 2) were often two sides of the same coin, i.e. good communication and poor communication, the issues identified were presented by themes rather than by facilitators and barriers separately. Due to similar conclusions, previous research on facilitators and barriers to integrated care programmes followed a similar approach (RAND Europe, 2012; Mackie and Darvill, 2016). Similar to the methods applied by Ismail *et al.* (2015), Ignatowicz *et al.* (2014), and Moffat *et al.* (2006), data collected across the different stakeholder groups were used to generate the themes in this qualitative research. Using NVivo 11 enabled me to match the coded data to participants, and therefore, to compare the views and experiences of interviewees and to identify outlying perspectives.

Themes and sub-themes were supported by verbatim quotations from participants, and it was clarified at the end of each quote to which stakeholder group (e.g. GP, manager, navigator, service user, or service provider) participants belonged. When additional text is included in quotes, for example for the purpose of clarification, the additional information is written in italics and placed in square brackets. For example: ‘They [*the navigators*] were supportive.’ Repetitions, such as ‘I mean, I mean, ehh, I mean, ehh’ or irrelevant units of speech had been omitted from supporting quotations. To show where words have been removed three dots in round brackets are used. For example ‘I mean (...)’. When names or any other identifiable information was removed from the transcripts to protect the privacy of interviewees, the description of the removed information will be placed in round brackets. For example: ‘Susan was helpful’ will be presented as ‘(The navigator) was helpful’.

6.3.6 Self-reflection

It is important for a qualitative researcher to reflect upon and articulate his or her background, philosophical stance, theoretical underpinning of the study, and data collection experience, as they inevitably form a filter through which the data will be examined and analysed (Pope, Ziebland and Mays, 2000; Sutton and Austin, 2015). In order to produce qualitative data, researchers need to engage with respondents, and hence, turn themselves into a research tool (Barbour and Barbour, 2003). As transcripts are the raw data of the research, qualitative researchers have to make sense of the data by structuring and interpreting them, building up an argument, and considering alternatives and exceptions (Pope, Ziebland and Mays, 2000; Barbour and Barbour, 2003). Hence, research findings cannot be detached from the data

collection and analysis process, as well as the researcher's reasoning and background. Stating and acknowledging what the researcher's filters are, enables readers to contextualise the work (Sutton and Austin, 2015).

Philosophical stance and theoretical underpinning of the study

This study was underpinned by the RMIC and critical realism. Thus, driven by the RMIC, the views of multiple stakeholder groups and the complexity of implementing and delivering SP were considered during the data collection, analysis, and interpretation process. Also, when the service user outcomes were explored qualitatively, the RMIC informed my perspective that the service user outcomes cannot be viewed in isolation from the implementation and delivery process. In addition, data analysis and interpretation was driven by the critical realist stance. Therefore, throughout the data collection, analysis, and interpretation stage I aimed to understand, in addition to the personal experiences and views, the factors that may have influenced the experiences and behaviours of the participants. Lastly, in line with the critical realist paradigm, I did not prioritise one method above the other, and aimed to benefit from the strengths of each applied method to achieve the aim and objectives of the study.

Reflection on the interview process

As a funded PhD student working in collaboration with the SP team in Luton from the early implementation phase, I felt that I had an understanding of the context, implementation, and delivery of the SP service. In addition, before I conducted the interviews, I attended numerous meetings and events with key stakeholders and I was a member of the steering group that met every two to four weeks. For this reason, when interviewing managers/decision-makers, navigators, and other key stakeholders involved in the implementation and delivery of the service, the role adapted was that of a fellow professional, an 'insider', who was interested in their experiences and views but at the same time had an understanding of the Luton SP programme. This had the advantage of enabling me to pose incisive follow-up questions and to create a more familiar environment and less artificial situation. The interview with key stakeholders, in which I had an 'insider' position, felt more like a one directional conversation, with me adopting a relatively passive position asking questions, listening, and probing. However, there was a possibility that respondents saw me as a member of the SP team, which could discourage open and authentic responses (Blythe *et al.*, 2013). As some of the key stakeholders were leading the implementation and delivery of the SP service, their anxiety to show the SP programme in a good light may have meant that stakeholders focused on more positive aspects than outlining the challenges and things that went wrong (Enosh, Ben-Ari and Buchbinder, 2008). Furthermore, there was a possibility that my ability to effectively question taken-for-granted assumptions, such as their role and responsibilities in the

SP programme or explaining the pathway of the SP programme, was compromised (Blythe *et al.*, 2013). I was conscious of these dangers, particularly when interviewing leading stakeholders and those with whom I attended other meetings or worked on specific programme related tasks as an ‘insider’ researcher. I tried to overcome these possible limitations by interviewing as many stakeholders as possible to capture different perspectives and views, in order to develop a comprehensive understanding. Secondly, I emphasised immediately before the interview that all information was confidential and would be anonymised, i.e. all identifiable information, such as names, will be removed from the transcripts, to encourage natural and open answers. Furthermore, I used a strategy that expressed understanding but asked for explanation or clarification for the purpose of the interview, to effectively question taken-for-granted assumptions. To get participants to clarify their statements, I used probing questions such as ‘Can you explain please what you mean with ...?’. This encouraged participants to expand and elaborate on their answers and prevented me from relying on what I assumed they were referring to (McEvoy, 2001).

When interviewing service providers, health professionals, and service users, I adopted the role of an ‘outsider’ researcher and an interested listener who has a good understanding of the Luton SP programme, but was keen to learn as much about the participant’s experiences and views as possible. This had the advantage of putting people at ease, as I was interested in their experiences and views and wanted to learn from them. Furthermore, that I was perceived as an independent researcher may have encouraged service providers to disclose and provide open and honest answers to my questions. As navigators, the project manager, and CCG members were involved in the recruitment of health professionals, service providers, and service users, there was an underlying expectation that I know the SP team in Luton, which was reflected by the use of first names when referring to people. This created a less artificial situation and turned the interview into a one directional conversation, me adopting a more passive role, asking questions. Establishing rapport and a familiar environment, as well as my good understanding of the service, enabled me to pose incisive follow-up questions to gain deeper insights.

I believe that I had learnt to talk to people with different backgrounds in ways that were appropriate for the situation. My active listening skills enabled me to identify what aspect of the topic was important for the interviewees, which aided the follow-up of statements to explore in depth. The face-to-face nature of the interviews enabled me to respond to facial expressions of, for example, puzzlement, to body language, for example nodding or face palming, and to hand gestures, for example showing the fragmentation between multiple sectors.

As I knew about some challenges the SP programme was faced with, I found it challenging at the beginning to keep to the passive position during the interview process, rather than engaging in an active discussion with the interviewees. I realised that after transcribing the first interview, the day after it was conducted. This enabled me to improve my interview style for the following interviews.

6.3.7 Rigour

The term 'rigour' refers to the robustness and credibility of study methods and can be defined as the criteria for trustworthiness of data collection, analysis, interpretation, and presentation (Rychetnik *et al.*, 2004; Prion and Adamson, 2014; Hays *et al.*, 2016). Hence, rigour generally refers to the steps taken to ensure the quality of the final research product (Laher, 2016). In qualitative research, issues of rigour is a debated topic among methodologists and there is no consensus of what constitutes a 'trustworthy' (the analogous for rigor in qualitative research) qualitative study (Hadi and Closs, 2016; Hays *et al.*, 2016). Rolfe (2006) highlights that there are three main opinions in the literature on how best to describe the rigour in qualitative studies. The different ontological and epistemological perspectives of researchers underpin these three opinions (Hadi and Closs, 2016). The first view (positivist) advocates the adoption and application of positivist terminologies used in quantitative research, such as validity and reliability, in qualitative studies (Rolfe, 2006; Hadi and Closs, 2016). The second view (critical realist) rejects the use of these positivist criteria in qualitative studies because of the differences in the philosophical paradigms underpinning the two methods (Rolfe, 2006; Hadi and Closs, 2016). This view promotes the use of alternative terminologies, such as those proposed by the qualitative research pioneers Lincoln and Guba (1985), namely: credibility, transferability, dependability, and confirmability. Credibility refers to the confidence in the overall believability and truth value of the study's findings (Jeanfreau and Jack, 2010). It is related to the steps taken to ensure that the data is a true reflection of the experiences and views of participants (Vivar, 2007). Transferability relates to the applicability of the study findings to other populations in different contexts (Prion and Adamson, 2014). Dependability refers to the degree of consistency if the research is repeated and is therefore related to the transparency of the research process (Vivar, 2007; Prion and Adamson, 2014). Confirmability refers to the extent to which the findings of a study are shaped by the participants' perceptions and not researcher bias, motivation, or interest (Amankwaa, 2016; Hays *et al.*, 2016). These criteria are commonly used to judge the rigour in qualitative studies (Prion and Adamson, 2014; Hays *et al.*, 2016). The third view (interpretivist) challenges the idea that a single pre-determined criterion is applied to judge the rigour of qualitative studies, as qualitative

research includes a range of research methods, which are underpinned by different research paradigms and theories (Rolfe, 2006; Hadi and Closs, 2016).

The criteria used to judge the rigour in a study need to be congruent with the methodological approach that has been employed, including the researcher's philosophical standpoint (Appleton and King, 2002; Hadi and Closs, 2016). As critical realism provides the philosophical ground for this study, issues of rigour in this qualitative study are addressed by the criteria suggested by Lincoln and Guba (1985). It is also important that the methodological approach and methods of a study allow relevant strategies (from a philosophical stance perspective) to promote rigour (Stanley and Nayar, 2014). For example, realists such as Pawson and Tilley (1997) argue that a major aspect of promoting the credibility of studies is to recognise that different stakeholders have different perspectives and views about a programme's implementation process and outcomes. Thus, from a critical realist perspective, involving different stakeholder groups promotes the credibility of studies (Porter, 2007). Table 3 outlines how credibility, transferability, dependability, and confirmability were addressed in this qualitative study. Table 4 provides definitions of terms used in Table 3.

Table 3: Issues of rigour in qualitative research

Criteria	Research strategy in this study
Credibility	<ul style="list-style-type: none"> • Purposeful sampling of participants (Tuckett, 2005) • Various stakeholder groups included (Mays and Pope, 2000) • Prolonged engagement (partly) (Lincoln and Guba, 1985; Hadi and Closs, 2016) • Self-description/ Reflexivity (Tuckett, 2005; Darawsheh, 2014; Hadi and Closs, 2016) • Peer debriefing (Lincoln and Guba, 1985; Hadi and Closs, 2016) • Thick descriptions (Hadi and Closs, 2016) • Interviews audio-recorded and transcribed verbatim (Seale and Silverman, 1997) • Transcripts checked for accuracy (Vivar, 2007) • Use of NVivo software to assist qualitative data analysis (Seale and Silverman, 1997) • Atypical perspectives included (Mays and Pope, 2000; Tuckett, 2005)
Transferability	<ul style="list-style-type: none"> • Purposive sampling strategy (Tuckett, 2005) • Thick descriptions (Lincoln and Guba, 1985; Tuckett, 2005; Hadi and Closs, 2016) • Audit trail (Hadi and Closs, 2016)
Dependability	<ul style="list-style-type: none"> • Developing a research protocol of the research design (Sarma, 2015) • Inquiry audit (Lincoln and Guba, 1985) • Audit trail (Lincoln and Guba, 1985) • Self-description/ Reflexivity (Darawsheh, 2014)
Confirmability	<ul style="list-style-type: none"> • Self-description/ Reflexivity (Lincoln and Guba, 1985; Hadi and Closs, 2016) • Audit trail (Lincoln and Guba, 1985; Jeanfreau and Jack, 2010; Hadi and Closs, 2016)

Table 4: Definitions of terms used in Table 3

Audit trail	A transparent description of all aspects of the research process, involving the descriptions of sources and techniques of data collection, analysis, interpretations, and decision-making (Lincoln and Guba, 1985; Sandelowski, 1986). Transparent descriptions can be aided by keeping research journals throughout the research process (Tuckett, 2005).
Inquiry audit	A method in which researchers not involved in the research process (in this study PP1 and PP2 examiners) examine the process and product of the research study (Lincoln and Guba, 1985).
Peer debriefing	A method in which the researcher discusses the research methodology, data analysis, findings, and interpretations continuously throughout the research process with her/his supervisor to provoke critical thinking, question the researcher's interpretations, and provide additional perspectives and explanations (Lincoln and Guba, 1985; Hadi and Closs, 2016).
Prolonged engagement	Prolonged engagement at the side of research to develop contextual familiarity of the researcher and to gain participants' trust can help in obtaining more in-depth information from respondents (Sarma, 2015; Hadi and Closs, 2016). Given that the researcher was partly funded by the Luton Borough Council, she attended steering group meetings from the start of her PhD, which enabled her to engage with the navigators, most managers, and some service providers before the interviews were conducted.
Purposeful sampling	Participants are selected because they are likely to have and share their understanding and experiences which promotes truth-telling (veracity) (Tuckett, 2005).
Self-description/ Reflexivity	Transparent description of the researchers position within the study and how their background, theoretical underpinning of the study, philosophical stance, and contextual factors have influenced the research findings (Lincoln and Guba, 1985; Long and Johnson, 2000). Transparent descriptions can be aided by keeping research journals and field notes throughout the research process (Tuckett, 2005).
Thick descriptions	Requires the researcher to give details about the setting, inclusion/exclusion criteria, sample characteristics, and data collection and analysis methods (Hadi and Closs, 2016). This allows the reader to evaluate the degree to which the researcher's conclusions are transferable to other settings, situations, and populations (Appleton and King, 2002).

6.4 Quantitative methods

6.4.1 Outcome measures

There are two main outcomes of interest in the quantitative analysis of this study, mental wellbeing and energy expenditure due to physical activity. The measurement tools for these two outcomes are discussed in the following section.

Warwick-Edinburgh Mental Wellbeing Scale

The 14-item WEMWBS was developed in 2007 in the UK to measure mental wellbeing at a population level over the past two weeks (Ng Fat *et al.*, 2017). A (7-item) short version of the WEMWBS (SWEMWBS) was developed in 2009 (Ng Fat *et al.*, 2017), which has been used in this study. The SWEMWBS has been translated and validated in various languages, however, only the English version was used in this study. The SWEMWBS comprises seven positively worded items, asking participants how often they had been ‘feeling optimistic about the future’; ‘feeling useful’; ‘feeling relaxed’; ‘dealing with problems well’; ‘thinking clearly’; ‘feeling close to other people’; and ‘able to make up their own mind about things’ over the previous two weeks (Stewart-Brown *et al.*, 2009). Answers to each item are provided using a five-point Likert scale (‘none of the time’, ‘rarely’, ‘some of the time’, ‘often’, and ‘all of the time’) (Ng Fat *et al.*, 2017). The Likert scale represents a score for each item from one to five respectively, giving a minimum score of seven (lowest possible mental wellbeing) and maximum score of 35 (highest possible mental wellbeing) (Vaingankar *et al.*, 2017).

International Physical Activity Questionnaire

The IPAQ was developed in 1998 as an instrument for cross-national assessment of physical activity based on a global standard (Craig *et al.*, 2003). There is a long (31-item) and short (7-item) version of the IPAQ (Craig *et al.*, 2003), the latter being used in this study. The short version (IPAQ-SF) covers the frequency and duration of walking, moderate, and vigorous physical activities over the previous seven days, and a single-item question on the duration of week day sitting (Scholes *et al.*, 2016). The IPAQ-SF has been translated and validated in various languages (Craig *et al.*, 2003), however, only the English version was used in this study. The use of the IPAQ-SF has been recommended when data collection time is limited, as it is faster, easier, and more feasible to complete than the long version (Craig *et al.*, 2003; Scholes *et al.*, 2016). In accordance with the officially recommended guidelines, the results of the IPAQ can be presented as a score in metabolic equivalent (MET) minutes per week for each activity category separately or as a sum (IPAQ Research Committee, 2005). METs represent the energy expenditure of physical activities as a multiple of the resting metabolic rate (Spadano *et al.*, 2003). For the average adult, one MET is defined as the energy expended while sitting quietly (Gault, Elisabeth and Willems, 2017). MET minutes can be calculated by

multiplying the MET score of an activity by the minutes it was performed (duration) (IPAQ Research Committee, 2005). The recommended MET intensity values used to score IPAQ questions were vigorous (8 METs), moderate (4 METs), and walking (3.3 METs) (IPAQ Research Committee, 2005). To calculate MET minutes/week, the number of days (frequency) a physical activity was performed must be considered in addition to its duration. The recommended formulas (presented in section 6.4.3) for data processing and analysis of the IPAQ-SF (IPAQ Research Committee, 2005) were used in this study to calculate MET minutes/week from the IPAQ-SF results.

6.4.2 Data collection

In this study, navigators collected the quantitative data from service users at baseline (i.e. in the first appointment with the navigator) and post-intervention (i.e. in the exit interview immediately after the intervention). Thus, routinely collected secondary data were used for the analysis of this study. Ethics approval was provided by the University of Bedfordshire for the quantitative study (Appendix 11). The NHS ethics approval was not required to analyse this routinely collected and anonymised data.

Challenges to data collection

A shared IT system was planned to facilitate communication between front-line providers, process online referrals between providers, monitor attendance of prescribed services, and ensure standardised and complete data collection in the Luton SP programme. Due to significant delays in the development of the shared IT system, the programme was changed into a ‘paper based’ version, instead of electronic, to prevent significant delays to implementation (for more details see Chapter 3). The shared IT system was finalised at the end of the data collection period for this study and SP programme (February 2018), and therefore was never used in practice. A ‘paper based’ programme meant that referrals and data collection happened on paper. Navigators manually entered the baseline and post-intervention data, collected with the IPAQ-SF and SWEMWBS, into a Microsoft Excel sheet.

6.4.3 Data preparation

Stage I: Data selection and calculations of MET minutes/week

All available secondary data (stored in Microsoft Excel software) was reviewed and then decided, based on the fourth objective of the study, which data are included in the database. The following data was initially included: the individual identification number, gender, age, working status, ethnicity, reasons for referral into SP, types of referred activities, barriers to adherence, name of GP who made the referral, and the pre and post intervention scores of the SWEMWBS and walking, moderate, vigorous, and total MET minutes/week. Microsoft Excel

software was used to calculate the walking MET-minutes/week, moderate MET-minutes/week, vigorous MET-minutes/week, and total MET-minutes/week pre and post intervention, based on the following formulas provided for the computation of MET minutes per week for data collected with the IPAQ-SF (IPAQ Research Committee, 2005):

Walking MET minutes/week = 3.3*walking minutes*walking days

Moderate MET minutes/week = 4.0*moderate intensity activity minutes*moderate intensity days

Vigorous MET minutes/week = 8.0*vigorous intensity activity minutes*vigorous intensity days

Total physical activity MET minutes/week = Walking MET minutes/week + Moderate MET minutes/week + Vigorous MET minutes/week

Table 5 summarises the variables included in the database and the corresponding variable types.

Table 5: Representation of the initially included variables in the database and their type

Included variables	Variable types
Patient identification number	Categorical
Gender	Binary
Age at referral	Continuous
Employment status	Categorical
Ethnicity	Categorical
Reasons for referral into social prescribing	Categorical
Types of referred activities	Categorical
Dropout stage	Categorical
Barriers to adherence	Categorical
Name of GP who made the referral	Categorical
SWEMWBS pre-intervention score	Continuous
SWEMWBS post-intervention score	Continuous
Walking, moderate, vigorous, and total MET-minutes/week pre-intervention scores	Continuous
Walking, moderate, vigorous, and total MET-minutes/week post-intervention scores	Continuous

Stage II: Merging datasets

Three navigators used a separate Excel spreadsheet to collect data from service users. To create a single database for analysis, the relevant data of each spreadsheet were merged.

Stage III: Data cleaning

First, the pre- and post-intervention scores of the SWEMWBS and IPAQ-SF were checked for errors, using Excel. It appeared that navigators often entered information in text format explaining why data was not collected, such as: *'Unable to complete due to language barrier - pt (patient) did not understand questions'* or *'Pt (Patient) declined to complete.'* In addition, questions on duration of physical activity over the past seven days were often answered with *'not sure'*. In these cases, the entered text was manually deleted and data for the specific item treated as missing. Besides an agreed standard for reporting duration of physical activity in minutes, for example '60', in practice, data on duration was not collected in a standardised way. Durations of physical activity were reported, for example, as *'120mins'*, *'120'*, *'2hours'*, *'2h'*, or *'2hr'*. To ensure data is presented in a standardised way and fit for analysis, all scores were manually checked, and, if needed, adjusted to meet the standard.

In a second step, the socio-demographic characteristics of service users were checked for errors, using Excel. The high amount of typos and the lack of standardised reporting for ethnicity and employment status created another challenge to data cleansing. First, an alphabetically ordered list, without duplicates, was created of all categorical data entered for employment status, in order to correct typos. Then related groups were merged into one group by, for example, merging *'E'*, *'Working'*, *'employed'*, and *'full-time work'* into one group, referred to as *'working'*, and *'Stu'*, *'college education'*, *'Student'*, *'full time education'*, and *'studying'*, into another group, referred to as *'student'*. Using this method, the following eight groups were created: Working, self-employed, unemployed, carer, student, disabled and long-term sick, homemaker, and retired. For some individuals, more than one status was reported, for example, retired and carer, or working and carer. For the sake of analysis, the categories working, self-employed, and individuals having any of these options (e.g. being a carer and working) were grouped into a single category, referred to as *'working'*. All others were categorised as *'not working'*.

For the variable *'ethnicity'* a similar approach to data cleaning was employed, hence, an alphabetically ordered list of the categorical data, without duplicates, was created in Excel to gain an overview of the data. In addition to an extremely high prevalence of typos, various combinations of ethnicities or nationalities were reported. After correcting typos, the range and diversity of reported ethnicities (including nationalities) remained extremely large

(Appendix 20). Collecting data on ethnicity is standard practice in quantitative research, to understand, and adjust, for the characteristics of the study population. However, due to the lack of standardised reporting, this variable was not fit for analysis.

The lack of standardised reporting on reasons for referral into SP, types of referred activities, and barriers to service user adherence, resulted in exhaustive lists of data and potential categories (Appendix 21-Appendix 22). Various combinations of reasons for referrals and barriers to adherence were also used without following the agreed data collection standards (Appendix 21). In addition, instead of reporting the types of referred activities (i.e., following the data collection standard), the providers' or organisations' names were often entered in the data collection sheet. To protect the privacy of providers in the third sector participating in the Luton SP programme, no extracts of the data are displayed for the types of activities in the Appendix of this thesis. Data on reasons for referral to SP and types of referred activities were initially collected for two reasons:

1. To examine and compare the frequencies of reasons for referrals to SP (e.g. depressive symptoms, diabetes II, COPD) and types of onward referrals (e.g. physical, social, creative activity).
2. To conduct more specific analyses; For example, examining physical activity levels for service users who participated in physical activities only or examining mental wellbeing post intervention only for those referred to SP because of depressive symptoms.

As the quantitative analysis is part of a mixed methods study, quantitatively reported barriers to service user adherence were initially collected to triangulate the quantitative results with the qualitative findings of barriers to service user adherence. However, due to the lack of standardised reporting, the three variables (reasons for referrals, type of referred activities, and barriers to service user adherence) were not fit for analysis (Appendix 21-Appendix 22).

Although navigators were asked to report if patients did not engage with the programme (i.e. dropped out of the programme right after the referral without seeing the navigator) or dropped out at a later stage, this was not done consistently. It appears that one navigator did not report any dropouts at all, another navigator occasionally, whereas the other two reported dropouts more systematically. Moreover, due to navigator turnover, and long gaps between recruiting and training new navigators, many service users in the process were sent back to their GPs. Thus, it is unclear how many individuals dropped out of the programme, attended a navigator

appointment, and prescribed activities/services, and the variable is not included in the analysis.

To clean the categorical variable including all reported names of GPs who made a referral to SP, an alphabetically ordered list, without duplicates, was created in Excel. Then spelling errors were corrected and a standardised way to report the names of GPs (i.e Dr Name) applied, to ensure the variable is fit for analysis. The variables age and gender were checked for errors and included in the analysis. Table 6 displays the variables that were included in the final database and used for analysis in the current quantitative study.

Table 6: Final list of variables included in the analysis

Included variables	Variable types
Patient identification number	Categorical
Gender	Binary
Age at referral	Continuous
Working status	Binary
Name of GP who made the referral	Categorical
SWEMWBS pre-intervention score	Continuous
SWEMWBS post-intervention score	Continuous
Walking, moderate, vigorous, and total MET-minutes/week pre-intervention scores	Continuous
Walking, moderate, vigorous, and total MET-minutes/week post-intervention scores	Continuous

6.4.4 Data analysis

The aims of the quantitative research of this study were not aligned with those of positivist researchers to produce objective results that can be generalised across time, settings, and populations (Johnson and Onwuegbuzie, 2004; Zachariadis, Scott and Barrett, 2013). Instead, following the critical realist perspective, this study aimed to produce an understanding of patterns and trends in the data for the Luton cohort, which are assumed to be influenced by setting, implementation, involved individuals, and the dimensions outlined in the RMIC (Damschroder *et al.*, 2009; Moore *et al.*, 2014; Valentijn, Biermann and Bruijnzeels, 2016). The quantitative analysis was done with the aid of the Statistical Package for Social Sciences (SPSS) Version 23 (for descriptive analysis), OPENBUGS (for data collected with the IPAQ-SF measuring energy expenditure), and R (for data collected with the SWEMWBS measuring mental wellbeing).

Descriptive analysis

All included variables (see Table 6) were analysed and visually displayed (histograms, box-and-whisker plots, scatter plots) to identify outliers, and examine the distribution of variables, their frequencies, and patterns in the data. In addition, the outcome variables were tested for normality graphically (Normal Q-Q plots, histograms, and box-and-whisker plots) and numerically (standardised skewness kurtosis, and Shapiro-Wilk test) to inform further analysis (Rietveld and van Hout, 2017).

Mental wellbeing

Challenges to data analysis

The quantitative study to assess the service user outcomes of the Luton SP programme, was based on the repeated-measures design, also called within-subject design. In this study design, one group of participants is measured at two different time points, before the intervention (baseline) and after the intervention (follow-up). The key characteristic of repeated-measures design is that the same variable is measured twice for the same set of individuals (Kirkwood and Sterne, 2003). The main advantage of this design is that data is collected from the same individuals pre- and post-intervention, thus there is no risk that substantial differences between samples (e.g. in sex, working status, wellbeing) bias the results of the study (Gravetter and Wallnau, 2016). If researchers are interested in the change of the mean population difference score (μ_D) in related samples, the paired t-test is a common statistical procedure (Kirkwood and Sterne, 2003; Rietveld and van Hout, 2017). Previous studies have used the paired t-test to assess the change in mental wellbeing scores, collected with the WEMWBS, after the participation in a SP programme (Morton, Ferguson and Baty, 2015; Woodall *et al.*, 2018). The null hypothesis (H_0) for a paired t-test states that the mean difference for the general population is zero. The alternative hypothesis (H_1) states that the mean difference for the general population will not equal zero (Gravetter and Wallnau, 2016). In notation:

$$H_0: \mu_D = 0$$

$$H_1: \mu_D \neq 0$$

The paired t-test requires four assumptions, for which the data were tested (Kirkwood and Sterne, 2003; Rietveld and van Hout, 2017):

- 1) The dependent variable is measured on a continuous scale (i.e. interval or ratio)
- 2) The same subjects are presented in both groups (matched pairs)

- 3) There are no extreme outliers in the difference scores (Difference (D) = post-intervention score – pre-intervention score) between the two related groups
- 4) The population distribution of the difference scores is approximately normally distributed

A new variable of the difference between the pre and post SWEMWBS scores (D) was computed to test the third and fourth assumption of the paired t-test (Dimitrov and Rumrill, 2003; Rietveld and van Hout, 2017). The fourth assumption of a paired t-test (i.e. that the differences between the pre and post scores is normally distributed) was violated (see Chapter 9 Figure 10). Violating the normality assumption can lead to unreliable results of the paired t-test and inferences with low power (Edgell and Noon, 1984). Thus, besides its frequent use, the paired t-test is not an appropriate method to assess the difference between SWEMWBS mean scores pre and post intervention for this sample. If the normality assumption is violated, the Wilcoxon signed rank test, which is the non-parametric counter part of the paired t-test and independent from the shape of the distribution (expressed in parameters like normality, variance, skewness, etc.), is often used as an alternative (Amin Jaradat *et al.*, 2016; Rietveld and van Hout, 2017). However, the Wilcoxon signed rank test's assumption of a symmetric distribution of the differences is violated (see Chapter 9 Figure 11) (Rietveld and van Hout, 2017). Thus, it is not an appropriate non-parametric alternative for this study sample.

Skew-Normal regression

Given that the commonly used paired t-test and Wilcoxon signed rank test are not feasible to assess the change in the SWEMBWS score between pre and post measures for this study sample, a regression approach using a Skew-Normal (SN) distribution was applied to analyse the asymmetric data. The SN distribution is an extension of the Normal distribution for skewed data, which allows for model building, estimation, and hypothesis testing (Figueiredo and Gomes, 2013). The extra parameter α in an SN distribution controls the skewness (Counsell *et al.*, 2011).

The SN regression model is as follows:

$$\text{Difference}_i = \beta_0 + \text{error}_i$$

Where difference represents the pre-SWEMWBS score subtracted from the post-SWEMWBS score for the i th individual ($i = 1, \dots, 63$).

Statistical and clinical relevance

When interpreting the results both statistical and clinical relevance was considered (Leung, 2001; Skelly, 2011). Statistical significance measures the likelihood that the observed difference in SWEMWBS scores pre- and post-intervention is 'true' rather than due to chance (Kirkwood and Sterne, 2003), whereas clinical significance relates to the magnitude of the observed effect and whether the observed change in SWEMWBS scores is meaningful in practice (Skelly, 2011; Putz. R., O'Hara, K., Taggart, F. and Stewart-Brown, 2012). P-values and confidence intervals (CIs) are commonly used measures of statistical significance (Kirkwood and Sterne, 2003). Previous studies and SWEMWBS guidelines suggest that the best estimate for a meaningful change in SWEMWBS scores is three or more points difference, between baseline and post-intervention (Maheswaran *et al.*, 2012; Putz. R., O'Hara, K., Taggart, F. and Stewart-Brown, 2012).

Power and sample size calculations

Four navigators of the Luton SP programme collected the data from service users for this study. Given that the data was routinely collected in a 'real life' programme, I had no influence on the number of patients included in the study (i.e. the sample size). Therefore, conducting sample size calculations at the design stage to determine the number of participants required for sufficient power (conventionally set at 80%) for the study, was not feasible (Noordzij *et al.*, 2010). The power represents the probability of avoiding a false-negative result (type II error), or in other words, the chance of correctly rejecting a null hypothesis (Noordzij *et al.*, 2010). Although I could not influence the number of service users in the sample, it would have been useful to conduct sample size calculations to gain an understanding about the required sample size for 80% power of the study and to achieve a result significant at the 5% level. However, to date, no statistical package exists to conduct sample size and power calculations for analysis based on the SN distribution.

Energy expenditure

Challenges to data analysis

The presence of many zeros, a relatively small sample size due to high loss of follow-up, and non-normality created several challenges to the analysis of the data collected with the IPAQ-SF. These challenges are discussed in more detail in the following sections.

There was a high prevalence of zeros in the data obtained from the IPAQ-SF, especially for moderate and vigorous MET minutes/week, due to low physical activity levels in the study sample. The presence of a large number of zeros in datasets creates challenges for analysis, as they cannot be justified by standard distributions and may prevent the transformation of the

data, for example log transformations (Kirkwood and Sterne, 2003). To overcome this challenge, previous studies analysing data obtained from the IPAQ, recoded MET values of zero into 0.1 (Lee, Xiang and Hirayama, 2010) or categorised the data to create dichotomous variables for logistic regression models (Royston, Altman and Sauerbrei, 2006; Xu, Zhu and Han, 2017). However, these methods are likely to bias the results and lead to loss of information (Royston, Altman and Sauerbrei, 2006; Xu, Zhu and Han, 2017).

Data collected with the IPAQ-SF for the Luton cohort were extremely incomplete. The analysis of small datasets can result in power issues and biased parameter values (Schoot *et al.*, 2015). There can be a high level of uncertainty in samples with small sizes, which besides a massive effect can result in too large p-values and CIs to reject a null hypothesis (Zyphur and Oswald, 2015).

The distributions of the variables walking, moderate, vigorous, and total MET-minutes/week pre- and post-intervention, obtained from the IPAQ-SF data were positively skewed and over-dispersed. In addition, the distributions of the differences in walking, moderate, vigorous, and total MET-minutes/week (difference (D) = post-intervention scores – pre-intervention scores) were non-normally distributed, non-symmetric, and contained a number of outliers (Appendix 23). Thus, the assumptions of the paired t-test and Wilcoxon Signed Rank test, the non-parametric alternative to the paired t-test, were violated (Rietveld and van Hout, 2017). Therefore, these statistical methods are not appropriate for the analysis of the skewed, over-dispersed data.

To overcome the discussed challenges and specifically the high number of zeros in the data, the Bayesian approach, and more specifically a zero-inflated negative binomial model was used to analyse the data obtained from the IPAQ-SF. The Bayesian approach, and how it compares to the frequentist approach, will be discussed in more detail in the following section.

Bayesian versus frequentist approach to statistical data analysis

Quantitative researchers in social and health sciences have historically relied on the frequentist approach to statistical analysis, including maximum likelihood, null hypothesis significance testing, p-values, and CIs (Kirkwood and Sterne, 2003; Zyphur and Oswald, 2015). However, the use of Bayesian methods for data analysis in social and health sciences is increasing (Neelon, O'Malley and Normand, 2010; Kruschke, Aguinis and Joo, 2012; Van de Schoot *et al.*, 2014; Zyphur and Oswald, 2015). There are fundamental differences

between the Bayesian and frequentist approach, relating to probabilities, estimations, and inferences that will be discussed in this section.

Probabilities quantify the uncertainty of data (Zyphur and Oswald, 2015). However, there are fundamental differences in the meaning of probability between the frequentist and Bayesian approach. Frequentists associate probability with the frequency of an event in the long run, and therefore reference the probability of observed data (Zyphur and Oswald, 2015). For frequentists, the data carry uncertainty in the form of a sampling distribution, assuming that only sampling errors affect results (Zyphur and Oswald, 2015). The p-value reflects the probability of finding the observed, or more extreme results, assuming that the null hypothesis is true (Kruschke, Aguinis and Joo, 2012). In contrast, Bayesian probability references the probability of parameters (Zyphur and Oswald, 2015). Uncertainty in the effect of parameters is quantified by estimating its probability across a range of values (Zyphur and Oswald, 2015). Therefore, the Bayesian approach allows direct probabilistic statements about parameters based on the observed data (Zyphur and Oswald, 2015). Another key feature of the Bayesian approach is that everything that is known before observing the data (the prior), can be combined with the information from the observed data (the likelihood), resulting in updated knowledge about the parameter (the posterior) (Schoot *et al.*, 2015). The prior information and the observed data are combined via Bayes' theorem to form the posterior distribution (Van de Schoot *et al.*, 2014). Thus, in contrast to the frequentists' approach to analysis, which usually starts with a null hypothesis that $\beta = 0$, the Bayesian approach can start with a prior belief about the likely values of the population parameters (Horry *et al.*, 2018). The information for the prior distribution can be based on findings from a meta-analysis, previous studies with comparable research populations, a pilot study and theoretical predictions (Zyphur and Oswald, 2015). If a prior distribution is based on existing knowledge, it is referred to as an informative prior distribution (Van de Schoot *et al.*, 2014). If no existing knowledge is available or used, the distribution is referred to as a non-informative prior distribution (Van de Schoot *et al.*, 2014). In the Bayesian literature, the use of non-informative priors is referred to as objective Bayesian statistics, as the variance of the posterior distribution is not influenced by existing knowledge (Schoot *et al.*, 2015). Specifying a flat prior distribution allows only the data (the likelihood) to determine the posterior results (Zyphur and Oswald, 2015). Such flat prior distributions specify that no parameter values are more probable than others (Zyphur and Oswald, 2015).

Another difference between the frequentist and Bayesian approach is the treatment of observed data and unknown parameters. Bayesians treat observed data as fixed and parameters as unknown and random across a range of possible values (Zyphur and Oswald,

2015). This is different in the frequentist approach, where data is treated as random and the parameters are assumed to be unknown and fixed (Zyphur and Oswald, 2015). Hence, frequentists assume that there is only one true, but unknown, population parameter in a population (e.g. one true mean, one true regression coefficient), whereas Bayesians treat all unknown population parameters as uncertain and describe them based on a probability distribution (Van de Schoot *et al.*, 2014). Therefore, in Bayesian terms, the parameter is not a value that we try to estimate, but a set of possible values with their corresponding probabilities.

In the Bayesian approach, statistical inferences are based on the posterior probability distribution. The Bayesian counterpart of the frequentist confidence interval is referred to as credible interval or posterior probability interval (PPI) (Kirkwood and Sterne, 2003). The PPI is the 95% probability that in the population the parameter lies between the two values (Van de Schoot *et al.*, 2014). Frequentists can estimate the strength of evidence to reject the null hypothesis, but cannot say anything about the probability of parameters (Zyphur and Oswald, 2015). By using Bayesian posterior probabilities, a direct statement about the probability of parameters can be made (Zyphur and Oswald, 2015). However, Bayesians do not take the mean as the basis for interpretation, instead they use the whole distribution (i.e. analyse its spread across the negative/positive territory) to estimate where the parameter could be (95% PPI), to explore associations with covariates, and their likelihood (Van de Schoot *et al.*, 2014). An advantage of Bayesian analysis is that, in contrast to frequentist approaches to estimations, it is able to handle more complex models, such as the Bayesian zero-inflated negative binomial model, efficiently (Van de Schoot *et al.*, 2014).

Lastly, in contrast to the frequentist approach, Bayesian analyses do not require large samples (Neelon, O'Malley and Normand, 2010). Therefore, it is a standard choice to analyse smaller datasets without losing power and while retaining precision (Schoot *et al.*, 2015). Table 7 provides an overview of the discussed similarities and differences between frequentist and Bayesian statistics.

Table 7: Overview of the similarities and differences between frequentist and Bayesian statistics (Kirkwood and Sterne, 2003; Van de Schoot *et al.*, 2014)

Characteristics	Frequentist statistics	Bayesian statistics
Inclusion of prior knowledge	No	Yes
Null hypothesis testing	Yes	No
Probability	Probability of observed data	Probability of a set of parameters
P-value	The probability (p-value) of observing the same or more extreme data, assuming that the null hypothesis is true	Not used to test a null hypothesis
Nature of the parameters in the model	Unknown but fixed	Unknown and random
Population parameter	One true value	A distribution of values reflecting uncertainty
Uncertainty is defined by:	The sampling distribution based on the idea of infinite repeated sampling (possibility of a sampling error)	Probability distribution for the population parameters
Estimated intervals	Confidence interval: Over an infinity of samples taken from the population, 95% of these contain the true population value	Credible interval: A 95% probability that the population value is within the limits of the interval
Requirement of relatively large sample sizes	Yes	Not necessarily

Zero-inflated negative binomial model

The negative binomial regression model is a generalisation of the Poisson regression model (Garay *et al.*, 2015). Negative binomial regression models are more flexible than Poisson regression models in accommodation of over-dispersion (when the variance significantly exceeds the mean) (Garay *et al.*, 2015). They allow for over-dispersion by introducing an unobserved heterogeneity term for each observation in the conditional mean of the Poisson model (Greene, 2008). The negative binomial model is a standard choice for over-dispersed count data (Greene, 2008).

Due to the excess of zeros in the data, that can't be justified by standard distributions, a zero-inflated count model needs to be applied. Zero-inflated count models handle zero-inflated count data (the excess of zeros) in addition to allowing for over-dispersion (Erdman *et al.*, 2008). There are two possible data generation processes for each observation i at time t (pre-intervention or post-intervention) in zero-inflated models, and the result of a Bernoulli trial determines which process is used (Erdman *et al.*, 2008). For observation i , process one is

chosen with probability $p_{i,t}$ and process two with probability $(1-p_{i,t})$ (Garay *et al.*, 2015). Process two generates only zero counts, whereas process one generates non-zero counts from either a negative binomial model or Poisson model (Erdman *et al.*, 2008). Due to the characteristics of negative binomial distributions discussed in the previous paragraph, the zero-inflated negative binomial distribution is more appropriate for zero inflated over-dispersed count data than zero-inflated Poisson distributions.

Data on physical activity with the IPAQ-SF were collected from a relatively small sample pre-intervention and post-intervention. To model the over-dispersed, zero-inflated count data for a relatively small dataset, the Bayesian zero-inflated negative binomial model has been applied in this study. Similar models were used before in health research, for example, to analyse psychiatric outpatient service use (Neelon, O'Malley and Normand, 2010). The Bayesian zero-inflated negative binomial model can be fit in standard Bayesian software packages such as OPENBUGS, which was used for the present analysis.

Modelling

First level of modelling: Zero-inflated negative binomial distribution for the MET score

First, the equation for the mean MET score (both pre- and post-intervention) is defined:

$$E(MET_{i,t}) = \mu_{i,t}$$

The expected (E) $MET_{i,t}$ score is modelled as a mixture of a non-zero value (with probability $p_{i,t}$) and a zero value (with probability $1-p_{i,t}$). A gamma mixture of Poisson densities (Hardin and Hilbe, 2007) was used to parameterise the non-zero component through a Negative Binomial such that it is defined by a mean of non-zero scores $\mu_{i,t}^*$ and a non-integer dispersion parameter η . Then the zero-inflated distribution, using unknown probabilities $p_{i,t}$, was constructed:

$$MET_{i,t} \sim \begin{cases} NB(MET_{i,t} | \mu_{i,t}^*, \eta) & \text{with probability } p_{i,t} \\ 0 & \text{with probability } (1 - p_{i,t}) \end{cases}$$

The mean MET score $\mu_{i,t}$, for individual i at time t (where $t=0$ is pre-intervention and $t=1$ is post-intervention), will be a weighted average of the negative binomial mean $\mu_{i,t}^*$ and zero, with weights as the aforementioned probabilities.

Second level of modelling: The probability and mean MET scores

We assume that all covariates can impact the probability of non-zero MET scores ($p_{i,t}$) as well as the mean MET score when it is not zero ($\mu_{i,t}^*$). There are three components in each of these modelling levels: (1) mean scores; (2) individual-specific effects from their covariates; and (3) intervention effects.

The parameters of interest are the following:

- θ = Nonlinear effect of the intervention on the probability of having a non-zero value. If positive, the intervention has a significant effect to reduce the number of zeros.
- β_k and β_k^* ($k=1,2,3$) = Effect of the covariates (i.e., age, gender, and working status) on the non-zero mean MET score ($\mu_{i,t}^*$) and on the probability of non-zero ($p_{i,t}$), respectively.
- t = time, where $t = 0$ is pre-intervention and $t = 1$ is post-intervention

Model for the probabilities of non-zero MET scores: Logistic link with covariates

$$\text{logit}(p_{i,t}) = \beta_0^* + \beta_1^* * AGE_i + \beta_2^* * GENDER_i + \beta_3^* * WORKING STATUS_i + \theta * t$$

For logistic regression, the link function is the logit (log odds) function (Kirkwood and Sterne, 2003). Logit functions map probabilities from the range zero to one to the entire real line (Kirkwood and Sterne, 2003).

Model for the mean of the non-zero MET scores: Log link with covariates

$$\log(\mu_{i,t}^*) = \beta_0 + \beta_1 * AGE_i + \beta_2 * GENDER_i + \beta_3 * WORKING STATUS_i + \theta * t$$

A transformation of the outcome variable ($\log(\mu_{i,t}^*)$) was modelled, rather than the outcome itself ($\mu_{i,t}^*$). The advantage of modelling the $\log(\mu_{i,t}^*)$ is that the parameter θ has a multiplicative interpretation (i.e., it will allow us to calculate the percentage increase or decrease in the MET score, measured as a percentage versus the pre-intervention case) (Kirkwood and Sterne, 2003). This seems to be more reasonable than assuming a linear effect in which the number of minutes is increased by the intervention irrespectively of the original score. For example, if the intervention is associated with a move from 10 minutes (pre-intervention) to 20 minutes (post-intervention) in an individual's MET score (i.e.,

double), then we should expect a move from 60 minutes (pre-intervention) to 120 minutes (post-intervention), i.e., double, rather than a move to 70 minutes post-intervention.

Third level of modelling: The hyperparameters

The parameters of the prior distribution are referred to as hyperparameters (Van de Schoot *et al.*, 2014). There is no prior knowledge on MET scores of primary care patients' pre- and post-participation in a SP programme in the UK. Therefore, standard flat gaussian priors (non-informative priors) were used for the remaining parameters (Zyphur and Oswald, 2015). As in this case the prior mean is uninformative, (i.e. the variance of the posterior distribution is not influenced), the result obtained for the posterior mean would be approximately similar to the mean obtained with maximum likelihood estimation using a frequentist approach (Van de Schoot *et al.*, 2014).

Definitions

Interpretations of results focus on assessing evidence of directionality in relationships tested. In order to summarise those interpretations homogeneously across measures (i.e., Walking, Moderate, Vigorous, and Total MET scores), conclusions are built upon 95% posterior intervals. Strong evidence of relationships is reported when at least 97.5% of the posterior density falls in either positive or negative territory (i.e., when the 95% equal-tailed posterior probability interval reported is bounded by values with the same sign). Unclear evidence of a relationship is reported in all other cases. In a more purist Bayesian interpretation, the parameters of interest are random variables, and reported posterior distributions simply represent our posterior knowledge about them. Therefore, we define 'strong evidence' in this study when (at least) 97.5% posterior probability of the parameter of interest shares a common sign.

6.4.5 Rigour

In quantitative research, issues of rigour are traditionally measured by concepts of reliability, objectivity, internal validity, and external validity (generalizability) (Sarma, 2015; Amankwaa, 2016; Hadi and Closs, 2016). Reliability refers to the degree to which observations can be replicated when the study is repeated under the same conditions (Rychetnik *et al.*, 2004). Objectivity refers to the degree to which results are free of biases and the researcher's interests (Sarma, 2015). Internal validity refers to the degree to which the results of a study are correct for the sample of people being studied (Rychetnik *et al.*, 2004). External validity refers to the extent to which study results, i.e. causal relationships between variables, can be generalised to different measures, persons, settings, and times (Steckler and McLeroy, 2008). Positivist researchers aim to develop a body of knowledge that is context

free, timeless and generalisable (Appleton and King, 2002). As discussed in Chapter 4, critical realism appears to depart from an unconditional form of generalisations. It seeks to formulate ‘outcome patterns’ which reflect the researcher’s current understanding of the phenomenon under study in a specific setting, time, and population (Appleton and King, 2002). Therefore, in contrast to positivists, critical realists consider associations between quantitative variables as time and context specific ‘demi regularities’, rather than causal laws (Zachariadis, Scott and Barrett, 2013). For critical realists, external validity refers to the belief that mechanisms that caused an observable event in a specific context and under certain circumstances may also cause similar outcomes in other domains (Zachariadis, Scott and Barrett, 2013). Table 8 outlines how reliability, objectivity, internal validity, and external validity were addressed in this quantitative study.

Table 8: Issues of rigour in the quantitative study

Criteria	Research strategy in this study
Reliability	<ul style="list-style-type: none"> • Developing a research protocol of the research design (uncontrolled before and after study) • Description and justification of methodology and methods (Laher, 2016) • Description and use of validated data collection tools (Laher, 2016) • Description of study context and sample characteristics (Zachariadis, Scott and Barrett, 2013)
Objectivity	<ul style="list-style-type: none"> • Developing a research protocol of the research design • Description and justification of methodology and methods (Laher, 2016) • Reflexivity on philosophical stance
Internal validity	<ul style="list-style-type: none"> • Description and use of validated data collection tools (Laher, 2016) • Exploring the dataset for errors and omissions (Laher, 2016) • Representative sample for Luton cohort (in terms of age, gender, working status) (Steckler and McLeroy, 2008)
External validity	<ul style="list-style-type: none"> • Description of sample characteristics, study contexts, setting, and Luton SP pathway (Zachariadis, Scott and Barrett, 2013)

6.5 Ethics

6.5.1 Ethics approval

Ethics approval for this mixed methods study was provided by the University of Bedfordshire, Institute for Health Research (Reference IHREC691, November 2016) and the NHS research ethics committee (Reference 16/NE/0389, Project ID: 209616, November 2016).

6.5.2 Ethical considerations in research

Ethical decision-making during the research process ensures that participants' rights, dignity, safety, and wellbeing are protected (The British Psychological Society, 2014). Ethical guidance for health related research in the UK is provided by, amongst others, the Royal College of Nursing (Buchanan *et al.*, 2004), the British Psychological Society (The British Psychological Society, 2014), and the major research funding bodies such as the MRC (Medical Research Council, 2016). The codes of practice published by these bodies are underpinned by ethical principles, which serve as tools for making reasoned judgements (Richards and Schwartz, 2002; The British Psychological Society, 2014).

As explained by Beauchamp and Childress (2001), the four principles of respect for autonomy (respecting decisions made by the individual), beneficence (research should have a positive value for the individual or/and wider society), non-maleficence (research should cause no harm), and justice (participants should be treated equally and fairly) provide a useful framework for ethical analysis in the health profession and have frequently been used to analyse ethical issues in public health (Coughlin, 2008). These ethical principles underpin professional codes of practice such as the Nursing and Midwifery Code of Conduct (Nursing & Midwifery Council, 2015) and the Code of Human Research Ethics (The British Psychological Society, 2014). Within the framework of these ethical principles, informed consent, confidentiality, data protection, and respect for the privacy and dignity of individuals and communities are integral (The British Psychological Society, 2014; Nursing & Midwifery Council, 2015).

The majority of ethical scandals involving social science and health research have been biomedical and quantitative in nature (Ensign, 2003). Therefore, most guidelines for the ethical conduct of research with humans are written from the biomedical perspective and relate to quantitative research, making little specific reference to qualitative research (Richards and Schwartz, 2002; Ensign, 2003). Although the four ethical principles discussed above are relevant to both quantitative and qualitative research, they have been developed to address ethical issues in biomedical (and by default mainly quantitative) studies (Ensign, 2003; Coughlin, 2008). However, there are some ethical issues that are specific to qualitative research. A paper written by Richards and Schwartz (2002) highlights the ethical issues specific to qualitative health research, to provide guidance for qualitative researchers and ethics committees reviewing such research (Richards and Schwartz, 2002). These ethical issues include: Anxiety and distress, exploitation, misrepresentation, identification of the participants, and inconvenience to reach the research centre (Richards and Schwartz, 2002). The following section describes how the ethical issues in qualitative research, the four ethical

principles described by Beauchamp and Childress, and ethical issues evolving from the role of the researcher were addressed in this study. As the quantitative data used in this study was routinely collected and anonymised before I had access to it, ethical considerations concern primarily the primary qualitative research of the study.

6.5.3 Ethical considerations in this study

The ethical principle of respect for autonomy focuses on the right of self-determination (Coughlin, 2006). The conception of autonomy entails freedom from external constraints and voluntary decision-making (Beauchamp and Childress, 2001). In the present study, the respect for autonomy is protected by informed consent. Informed consent provision ensures that participants make a free and informed choice and give researchers the legal authorisation to proceed with the research (Royal College of Nursing Research Society, 2015). All individuals that participated in the primary qualitative research in this study needed to read an information sheet and signed that they understood their rights, the voluntary nature of participation, the nature and purpose of the research study, and the use of data (Richards and Schwartz, 2002; The British Psychological Society, 2014; Royal College of Nursing Research Society, 2015). The information sheet was written in a language appropriate to the potential participant group (Royal College of Nursing Research Society, 2015), therefore, two versions of the information sheet were produced, one for stakeholders involved in the implementation and delivery of SP (navigators, managers and decision-makers, GPs, and service providers in the third sector) (Appendix 5), and one for service users (Appendix 8). Informed consent was obtained immediately prior to the interview and there was time for discussion, clarifications, and possible questions of participants. At this stage, participants were also reminded that participation in the study is voluntary and that they could stop the interview at any point. In order to complete the referral of primary care patients to the Luton SP programme, GPs had to obtain consent from patients for sharing their contact details with the navigators and for the use of their anonymised data for service evaluation purposes.

To avoid that service users feel coerced into participation, it was clearly stated in the information sheet that participation is voluntary, confidential, and taking part will not affect the care they receive in any way. To recruit service users for this study, navigators were asked to send the recruitment pack to eligible service users or to hand it out to them at the end of routine appointments. I was aware about the risk that service users may feel obliged to participate in the study, as a result of the relationship with the navigator or because they fear that not taking part may affect the care they receive from the primary care team. To avoid that service users feel coerced into participation and to support the navigator in the recruitment process, guidelines for navigators were developed (Appendix 10). The guidelines were also

developed to ensure that consistent information is provided to service users (Appendix 10). The guidelines outlined the following points navigators should say when handing out the recruitment pack in person:

- 1) The information in the recruitment pack should be read carefully before deciding whether to participate in the study
- 2) Participation is voluntary
- 3) Participants can opt out at any time without providing any reason
- 4) The study is independent from the general practice and SP service and therefore their decision to take part will not affect the care they receive in any way
- 5) If service users have any questions regarding the study they should contact the researcher (Contact details are provided in the recruitment pack)

All the information in the guidelines was also clearly stated in the invitation letter and information sheet of the recruitment pack. Therefore, there was no difference in provided information between service users who received the recruitment pack via mail and those who received it from the navigator. All participants in the study were treated fairly and equally and I, as the researcher, had the responsibility to promote and protect their rights throughout the research process (principle of justice) (Beauchamp and Childress, 2001).

To protect the personal information and privacy of patients referred to the SP programme, navigators were asked to send out a recruitment pack, on behalf of the researcher, to eligible service users. The privacy and dignity of all participants in the study was respected, and I ensured that participants were not personally identifiable from the data, i.e., that all data used for this study was anonymised. Paperwork that contained personal data, such as the consent form, was kept in a locked filing cabinet on university premises in line with the Data Protection Act 1998. Any identifiable personal information in the audio-recordings was removed during transcription. The audio-recordings and anonymised data were stored on the researcher's password-protected laptop in a password-protected file. Rigorously protecting the privacy of participants and confidentiality of data is an important way to avoid potential harms and risks to individuals such as stigma or discrimination (the principle of non-maleficence) (Beauchamp and Childress, 2001; Coughlin, 2006, 2008). Before the interviews with stakeholders involved in the implementation and delivery of the Luton SP programme, I made clear that no identifiable data, such as names, will be released, but that the presented data in the form of quotes, will be matched to a stakeholder group.

As qualitative research aims at an in-depth understanding of an issue, it is often probing in nature (Richards and Schwartz, 2002). Although the primary focus of the study was not to discuss sensitive issues with participants, questions which pose a risk to participants' mental wellbeing and could lead to anxiety and distress depend on the personal biography and experiences and, therefore, cannot always be predicted accurately (Richards and Schwartz, 2002). Due to the open-ended nature of qualitative research and the discussion of topics related to personal experiences, decisions, and outcomes of the Luton SP service, sensitive issues related to an individual's health and wellbeing cannot be avoided reliably (Richards and Schwartz, 2002). I carried a list of contact details of sources of local support, to be able to respond if necessary. It was also agreed with the navigators that if I feel that service users' wellbeing or health is at risk, I could ask service users to contact the navigator for a follow-up discussion. Fortunately, the situation did not arise.

There might be a power imbalance between the researched and the researcher, so that participants could feel pressurised to participate in research or to answer (sensitive) questions (Richards and Schwartz, 2002). This power relationship and the open nature of qualitative research can potentially lead to harm and exploitation, as participants may reveal more information than they anticipated when consenting to the study (Richards and Schwartz, 2002). However, this problem is more likely to arise when the researcher is a health professional involved in the care of participants (Etherington, 1996), rather than an external non-medical researcher or like-minded professional, which were my roles in this study. In this study, I clearly outlined my role in the invitation letters and information sheet. To avoid that participants divulge more information than they feel confident with, I did not pressurise them to answer any questions and aimed to create an equal power relationship between the interviewer and interviewee.

In qualitative research, the experiences and identities of researchers affect the way in which the data are collected, analysed, and interpreted (Griffith, 1998; Couture, Zaidi and Maticka-Tyndale, 2012). When I interviewed participants I did not share experience with, hence I was positioned as an 'outsider', I adopted the role of a researcher, who has a good understanding of SP, but is interested in the experience and perspective of the interviewee. Having an 'insider' position had advantages but also provided some challenges for me in conducting the research. An advantage of being an 'insider' researcher was that the previously discussed ethical issue of power imbalances between the researcher and participants was minimised, as an insider researcher is often viewed on a more equal footing (Blythe *et al.*, 2013). Knowing that I share similar experience with participants enhanced the development of rapport and enabled reciprocity between the interviewee and me. However, it is possible that being

perceived as a member of the SP team, i.e. an ‘insider’ who knows the interviewees, their colleagues, and other people they worked with, discouraged honest and open answers to some of the questions. To reduce this risk, I emphasised before the interview that I will protect the individual’s privacy, respect confidentiality, and that all identifiable data will be removed from the transcripts, meaning that all data will be anonymised. Furthermore, it happened that interviewees felt uncomfortable criticising aspects of the service or discussing what hindered the implementation and delivery because they did not want to sound too negative or refer to other stakeholders in a negative way. To overcome this tension, I used questions such as ‘*What would you do differently if the SP service was to start again?*’ (Appendix 17), which put participants at ease and at the same time allowed me to collect relevant data for the research study. As most of the participants work or lived in Luton or London, where the interviews were conducted, it is unlikely that participants experienced high travelling costs or required a lot of time to reach the venue. I also adjusted my schedule to the participants’ schedule to agree on a date and time convenient for both parties.

Some scholars argue that the analysis and interpretation of qualitative data is inevitably influenced by the characteristics and preconceptions of the researcher (Richards and Schwartz, 2002). Therefore, there is the potential risk that qualitative researchers misinterpret the views of participants or take them out of context (Richards and Schwartz, 2002). This issue is particularly relevant to health service research, as most studies are designed to answer specific questions and are therefore strongly directed by preconceived theories and ideas (Richards and Schwartz, 2002). Constructing identities for participants, risks the misrepresentation of individuals’ perspectives and experiences and breaches respect for participants’ autonomy and self-identity (Richards and Schwartz, 2002). The risk of misinterpretation was minimised in this study by asking participants to explain or elaborate on their points during the interview, if it was not clear to me what they meant. In addition, I discussed the data analysis process with more experienced researchers and was supervised through the process by my academic supervisors. Additionally, I presented the theoretical underpinning of this study (Chapter 4), the philosophical stance (Chapter 5), and my position as a researcher (Chapter 6), which may have affected the data collection, analysis, and interpretation in this study.

A potential issue could be the expectations of the LBC, the body that partly funded my studentship, towards the research study and in particular the usage of findings. As I was conducting this research for my PhD study, my goal was to conduct high quality and robust research, which is time consuming. On the other hand, the LBC and decision-makers may be interested in more immediate and tangible results to inform commissioning and to improve

the implementation and delivery of the SP service. To manage the expectations of the funding bodies and steering group, I discussed the objectives of the study with them to ensure shared understanding of the objectives. In addition, I shared a Gantt Chart at the beginning of the study with the funders, so that it was clear when they could expect the results of the study to be available. In addition, I provided regular feedback about the process of the study and discussed any arising issues immediately, to make sure to manage the funder's and the steering group's expectations, while conducting rigorous research for my degree.

There might be no direct benefit to the participants of the study. However, there are potential benefits to the wider society. Findings of this study improved the implementation and delivery of the Luton SP programme, contribute to the evidence base on SP, and may help to improve the implementation and delivery of SP in the UK, which has the potential to improve the health and wellbeing of people.

6.6 Chapter summary

This chapter has presented the methods employed in the study. A systematic review was conducted to collect and synthesise data on factors affecting the implementation of SP programmes in the UK and potential service user outcomes (Objective 1). Semi-structured interviews were conducted with GPs, navigators, managers/decision-makers, and service providers in the third sector to explore factors affecting the implementation of the Luton SP programme (Objective 2). Semi-structured interviews were also conducted with GPs, navigators, and service users to explore factors affecting patient uptake and adherence to the Luton SP programme (Objective 3). For objective 4, semi-structured interviews were conducted with service users to explore experienced outcomes. In addition, a SN regression and Bayesian analysis was performed to assess the change in mental wellbeing and energy expenditure post-intervention, compared to baseline measures. Finally, the ethical considerations in health research, and specifically for this funded mixed methods study, were discussed. The following three chapters (Chapter 7-9) will present the findings and results of this study.

7 Chapter 7: Systematic review findings: Facilitators and barriers to the implementation of social prescribing in the UK

7.1 Introduction

This chapter presents the findings of the systematic literature review, which addressed objective 1: To identify and synthesise evidence on (i) factors that facilitate and hinder the implementation of SP programmes in the UK, and (ii) the impact of SP on service users in the UK. The chapter begins with a visual presentation of the study selection and a discussion of the methodological quality of included studies. The chapter then presents the findings for the primary and secondary outcomes by themes.

7.2 Objective 1: Systematic literature review

7.2.1 Study selection process

The titles and abstracts of 7676 records were screened. Of these, 234 records were considered potentially eligible and were assessed in full text. In total, 19 records met the inclusion criteria of the review (Figure 9). Most common reasons for excluding records included the absence of data on primary and secondary outcomes. Some reports on SP were progress reports and did not contain evaluative information. Another common reason was that interventions did not meet the inclusion criteria. For example, in some programmes referrals to SP were made by organisations beyond the health sector, such as community and voluntary organisations. In other interventions, health professionals referred patients directly to activities provided in the third sector without involving a navigator. In agreement with the findings of Kinsella (2015), this research found that many reports and articles referred to the same SP interventions. Multiple records that cited primary and secondary outcomes of the same SP interventions were put together. The records containing the most complete and relevant information were included, which were usually the original evaluation reports or primary studies. An adapted PRISMA flow chart depicting these results is presented in Figure 9 (Moher *et al.*, 2009a).

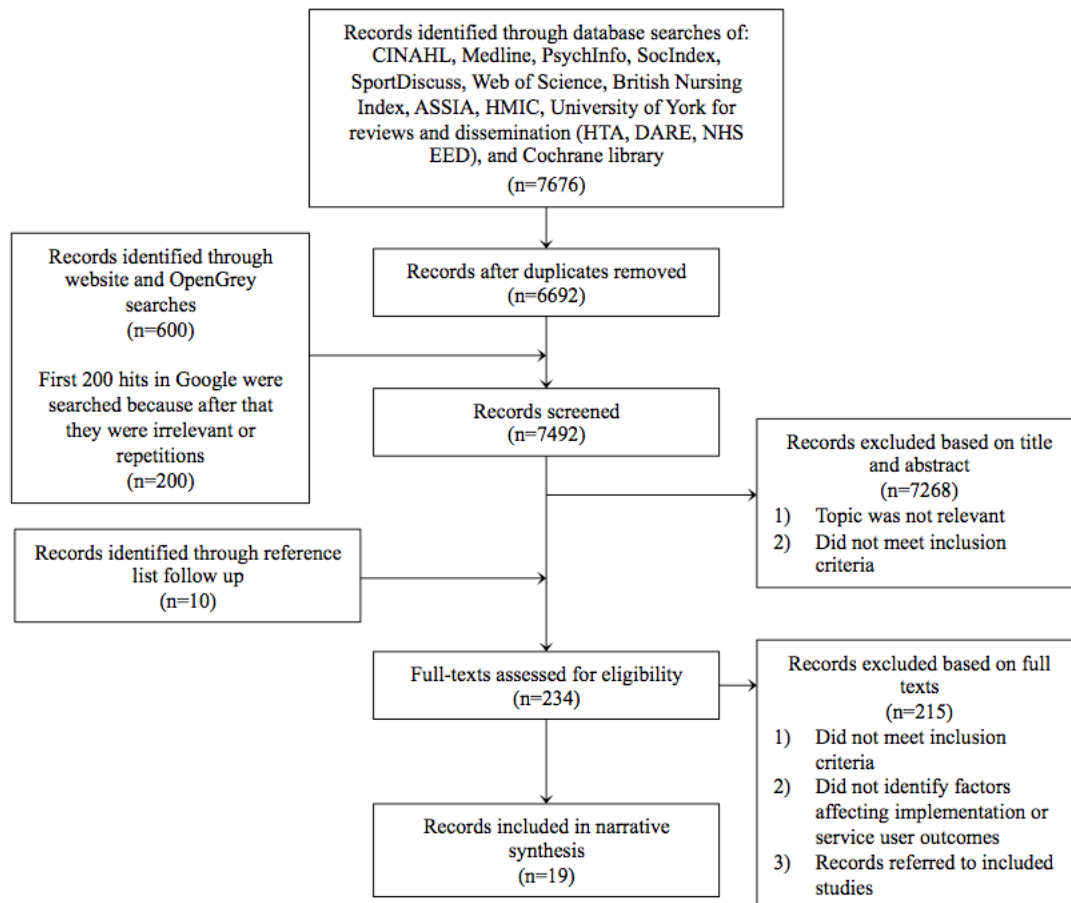


Figure 9: Adapted study selection flow diagram based on PRISMA (Moher *et al.*, 2009b)

In total, the included studies comprised of eight journal articles (Grant *et al.*, 2000; Grayer *et al.*, 2008; Vogelpoel and Jarrold, 2014; Carnes *et al.*, 2017; Loftus, McCauley and McCarron, 2017; Moffatt *et al.*, 2017; Whitelaw *et al.*, 2017; Skivington *et al.*, 2018), and eleven evaluation reports (Age UK and Age concern, no date; White, Kinsella and South, 2010; Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013; Kimberlee *et al.*, 2014; Baines, 2015; Wigfield *et al.*, 2015; Farenden *et al.*, 2015; The Health Foundation, 2015; Dayson *et al.*, 2016). The publishing date of the Age UK report is unknown (Age UK and Age concern, no date). With one exception (Grant *et al.*, 2000), all the other 17 included records were published in the last eight years, highlighting that SP is a relatively new phenomenon in the UK.

7.2.2 Quality appraisal

The quality of included studies and evaluation reports were assessed with the MMAT-V 2011. To assess the quality of quantitative studies, section two (randomised controlled studies), section three (non-randomised studies), or section four (descriptive studies), respectively, of the MMAT was used (Appendix 3). For appraising a qualitative study, the

first section of the MMAT was used. To appraise mixed methods studies, the first section was used to assess the qualitative component, section two, three, or four (as appropriate) to assess the quantitative component, and section five to assess the mixed methods component.

Most of the included records failed to attain higher quality scores as a result of a lack of details on methodology (Table 9). Most of the included evaluation reports did not provide detailed information on data collection tools, recruitment and sampling strategies, and the process of gathering and analysing data. Methodological information was often spread across evaluation reports and could be found, for example, in footnotes in small print or in the Appendix. In general, there was a lack of a structured and detailed methodology section in most evaluation reports of SP in the UK, which created a challenge to the quality appraisal of available evidence.

The major limitations of reviewed quantitative studies assessing service user outcomes were the small sample sizes, lack of comparable control groups (only one RCT (Grant *et al.*, 2000), and one non-randomised control study (Loftus, McCauley and McCarron, 2017)) were identified), and high loss of follow-up. Furthermore, the origin and validity of some data collection tools, used to assess service user outcomes, were not clear. None of the included quantitative studies conducted sample size calculations to determine the number of participants needed for sufficient power to demonstrate a change in outcomes.

None of the included evaluation reports considered how qualitative findings relate to the researchers' influence e.g. through their interactions with participants, their role, and perspectives. This could be explained by the fact that the underlying aim of evaluation reports is to inform practice and policy, rather than fulfilling the criteria of methodological quality appraised by the MMAT- V2011 and standards of academic journals.

The journal articles by Grant *et al.* (2000), Grayer *et al.* (2008), Carnes *et al.* (2017), Skivington *et al.* (2017), and Whitelaw *et al.* (2017) as well as the evaluation report by Brandling *et al.* (2011), were attained the highest quality scores (***) of the 19 assessed records (see summary of quality scores of the MMAT in Table 9). The evaluation reports by Dayson *et al.* (2016), Farenden *et al.* (2015), Kimberlee *et al.* (2014), White *et al.* (2010), and Wigfield *et al.* (2015), as well as the journal article by Voegelpoel and Jarrold (2014), Moffat *et al.* (2017) attained a quality score in the middle range (**) of appraised studies. The evaluation reports by Friedlie *et al.* (2012), The Health Foundation (2015), the ERS Research Consultancy (2013), and Baines (2015) attained the lowest quality score (*) of studies included in the review. However, there were no consistent similarities and differences

between the results and findings of higher and lower quality studies. The report by Age UK did not attain a quality score, as the two screening questions were answered with ‘no’ and ‘can’t tell’ that indicate that further appraisal may not be feasible or appropriate (Pluye *et al.*, 2011). The summary of the quality scores of records included in the review is presented in Table 9. The full quality appraisal process for each study by each criteria of the MMAT-V 2011 is presented in Appendix 3.

Table 9: Summary of quality scores for each included study calculated using the MMAT-V 2011

Author and date	Overall quality score
Brandling <i>et al.</i> , 2011	***
Grayer <i>et al.</i> , 2008	***
Grant <i>et al.</i> , 2000	***
Carnes <i>et al.</i> , 2017	***
Skivington <i>et al.</i> , 2017	***
Whitelaw <i>et al.</i> , 2017	***
Dayson <i>et al.</i> , 2016	**
Farenden <i>et al.</i> , 2015	**
Vogelpoel and Jarrold 2014	**
Kimberlee <i>et al.</i> , 2014	**
White <i>et al.</i> , 2010	**
Wiegfield <i>et al.</i> , 2015	**
Moffat <i>et al.</i> , 2017	**
Loftus <i>et al.</i> , 2017	**
Friedli <i>et al.</i> , 2012	*
The Health Foundation 2015	*
ERS Research and Consultancy 2013	*
Baines 2015	*
Age UK n.d	-

Scoring metrics: ‘-’= Further appraisal was not feasible as the answers to the two screening questions were ‘no’ or ‘can’t tell’ ‘*’=25%, ‘**’= 50%, ‘***’= 75%

Most evidence on the implementation and outcomes of SP programmes in the UK is based on observational quantitative descriptive studies and qualitative research. In addition, most evidence is available in the form of unpublished evaluation reports. This systematic review includes all initially identified 19 records, regardless of their quality scores, as to date more rigorous studies are lacking to provide evidence on the implementation, and service user outcomes of SP in the UK.

7.2.3 Primary outcomes

This section provides the findings from the narrative analysis, which aimed to identify barriers and facilitators to the implementation of SP. The following themes were identified: Operational processes, Navigator-ready surgeries, shared knowledge and understanding, communication and relationships, human resources, referral process to SP, patient uptake and adherence, and third sector resources.

Operational processes

Engagement of stakeholders

Early involvement of a wide range of stakeholders in the development of SP schemes was considered an enabler to implementation, as it promoted early understanding, motivation towards SP, enthusiasm, and feelings of involvement from the beginning (Whitelaw *et al.*, 2017).

Approach to implementation

Applying a phased roll out approach to implement SP interventions (i.e. changes are made over a period of time with a scheduled plan of steps) was identified as an enabler and believed to be essential for the successful implementation of SP programmes (Farenden *et al.*, 2015). A phased roll out approach promotes relationship building between partners, shared understanding of SP, and the roles of partners, which were perceived as essential for successful cross-organisational and multidisciplinary working (Farenden *et al.*, 2015). In line with this finding, the study by Brandling *et al.* (2011) found that a ‘lead in’ period (i.e. preparation phase) was required to establish groundwork, build relationships with stakeholders, define referral and assessment criteria, hold networking events, and develop a working practice (Brandling *et al.*, 2011; Whitelaw *et al.*, 2017). Having a ‘lead in’ period also seemed to foster shared understanding and awareness about SP, which (i) helped to consolidate the concept and ‘brand’ of SP, and (ii) to enhance the consistent image of SP to outsiders (Brandling *et al.*, 2011; The Health Foundation, 2015). It is important to plan a realistic ‘lead in’ time for setting up SP programmes, considering that it can take several weeks to set up initial meetings with GP practices (Age UK and Age concern, no date; Farenden *et al.*, 2015).

The SP programme in Brighton and Hove applied a ‘go live dates’ approach to initiate SP in general practices (i.e. following set dates to initiate SP in surgeries) (Farenden *et al.*, 2015). Following this approach, navigators and practice staff felt rushed into hosting SP without building relationships and trust between partners, developing shared understanding of

outcomes and expectations, or agreeing mutually effective working practices, which hampered the implementation of the programme (Farenden *et al.*, 2015).

Adaptability

Adaptability, i.e. hearing what stakeholders need from the programme and altering systems, processes, and communications accordingly during the development and implementation process, has emerged as one of the strengths of SP pilots and major enabler to implementation (Dayson, Bashir and Pearson, 2013; Farenden *et al.*, 2015; Whitelaw *et al.*, 2017). Dayson *et al.*, (2013) called this approach ‘action learning’, which is possible when a SP programme is set up as a pilot rather than a mainstream standardised service. A flexible approach turned out to be effective particularly when working in partnership with primary care surgeries, as each surgery is an unique organisation and may have different needs to implement and deliver SP (Farenden *et al.*, 2015). Having a flexible approach to surgery staff training, also improved responsiveness to SP and enhanced partnership working. Surgery staff’s availability differed, some surgeries were able to send most of their staff to an hour long training session on SP, whereas other surgeries could spare one staff member for 20 minutes (Farenden *et al.*, 2015). Although a flexible approach to training was generally perceived as beneficial, managers and navigators expressed concerns about a too flexible approach to training, as too little training resulted in low levels of understanding of SP in some surgeries (Farenden *et al.*, 2015).

Programme management

Regular implementation meetings, utilising for example the commonly used steering group approach, to discuss processes, arrange operational procedures, and react to challenges, facilitated the implementation and delivery of SP programmes (Farenden *et al.*, 2015). In a SP programme in Newcastle, no programme manager was assigned initially (ERS Research and Consultancy, 2013). In the Newcastle programme, the steering group consisted of a diverse group of stakeholders, and was responsible for the project development and management (ERS Research and Consultancy, 2013). Although the collaborative approach had been of some benefit, it contributed towards a delayed implementation and delivery of SP (ERS Research and Consultancy, 2013). The lack of a targeted approach to strategic and robust project management to undertake the coordination required for the project, resulted in less effective and delayed implementation (ERS Research and Consultancy, 2013). Moreover, the absence of a robust risk management system to be prepared for possible scenarios that could disrupt implementation, such as staff turnover, negatively impacted on the implementation process (ERS Research and Consultancy, 2013).

Support and supervision

The support of the practice manager in surgeries was vital for arranging meetings with GPs, to build relationships between the SP team and the general practice, and to increase awareness about SP during the ‘lead in’ time, implementation, and delivery phases (Age UK and Age concern, no date). Navigators in the ‘New Routes’ SP programme have received support and supervision from their employer (The Care Forum), the project steering group, and the community mental health team (Brandling *et al.*, 2011). Overall, navigators perceived this supportive structure as helpful and felt supported in the implementation of the pilot and delivery of their role (Brandling *et al.*, 2011). However, the diverse nature of the support structure required the adherence to multiple different interests of different stakeholders and organisations involved, which felt conflicting for navigators at some times (Brandling *et al.*, 2011). If volunteers were recruited as navigators in a SP programme, it turned out to be useful to seek support from third sector partners that have good knowledge and are more experienced in recruiting, training, and supporting volunteers (Farenden *et al.*, 2015)

The support levels offered to service users by volunteers in the Brighton and Hove programme differed, as some volunteers could accompany service users to activities during the week, whereas others had less time and were only available during their weekly shift in the general practice (Farenden *et al.*, 2015). This meant that accompanying patients to activities could only be offered on a case-by-case basis and needed to be adjusted to navigator’s availability, resulting in inconsistent available support for service users. In Newcastle, the absence of a clear and standardised support framework for navigators resulted in unmet service user expectations and disappointment (ERS Research and Consultancy, 2013). A clear framework for the support provided by navigators to service users, which is monitored and managed by the project manager and part of the partnership and service level agreements, was recommended to ensure consistent service user support (ERS Research and Consultancy, 2013).

Digital flagging systems

Previous SP programmes adopted a digital flagging system, which was designed to assist GPs to identify suitable patients for SP at a consultation with an on-screen message (Brandling *et al.*, 2011; ERS Research and Consultancy, 2013). The majority of health professionals participating in the SP programme in Newcastle considered the digital flagging systems as impractical to identify patients for SP (ERS Research and Consultancy, 2013). Health professionals reported that there are too many flags on the system already, and that the flags for SP popped up too often so that they were not longer noticed (Brandling *et al.*, 2011; ERS Research and Consultancy, 2013). Furthermore, health professionals stressed that SP is about

talking to people and seeing them and their health in a wider (non-medical) context, therefore, flagging, all eligible patients with a health condition did not help to identify eligible patients for SP (Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013).

Navigator-ready surgeries

‘Navigator ready’ (Farenden *et al.*, 2015, p.42) practices were crucial for the successful implementation of SP and to ensure that an effective and equitable service was delivered to service users (Farenden *et al.*, 2015). The preparation of surgeries to become ‘Navigator ready’ often took longer than anticipated and was identified as a major barrier to implementation (Brandling *et al.*, 2011; Farenden *et al.*, 2015). The following steps were recommended by Farenden *et al.* (2015) for a GP surgery to become ‘Navigator ready’:

1. It is important that the SP team meets the whole practice team (clinical and non-clinical staff) before SP commences. This could happen during a training session or practice meeting. The SP team should ensure they work flexibly when arranging a visit at the GP surgery.
2. A partnership agreement needs to be signed between the SP service and the primary care surgery hosting it.
3. GPs need to agree to make regular referrals to SP. Numbers of patients that can be seen by the navigator, within a certain timeframe, depend on their capacity and should be discussed with primary care team in advance.
4. Navigators should be treated as a member of the staff team. To ensure this happens, surgery staff needs to:

- Understand the scope of the SP programme and the navigator’s role, responsibility, and skills
- Provide a room for the navigator within the surgery, which is accessible for patients and allow meetings without interruptions. Co-location of navigators was an important element for the success of the formation of new integrated teams and joint working, as it promoted informal contact, relationship building, mutual understanding, trust, and continuous communication (The Health Foundation, 2015; Skivington *et al.*, 2018).
- Provide an induction for navigators, including available staff facilities, safety procedures, computer login in details, and telephone access in primary care surgeries
- Invite the navigators to relevant team meetings
- Clarify how and when the navigator can contact the GP directly
- Provide a lead staff member who can answer queries in relation to surgery systems and communications

- Provide a secure space for navigators to keep their files, working material, and confident records in the general practice

A key lesson learnt from the SP programme in Maryfield was that GPs are more likely to make regular referrals to SP and work with navigators, when the practice culture supports holistic and psychosocial approaches (Friedli, Themessl-huber and Butchart, 2012).

Shared knowledge and understanding

The importance of clinical and non-clinical primary care staff understanding what can be expected by each partner, the scope of SP, which patients to refer, how patients can be helped, and the capacity and skills offered by navigators were central for successful implementation of SP (Farenden *et al.*, 2015). Shared understanding of roles and responsibilities between partners and stakeholders across sectors was commonly identified as facilitator to early implementation, and if absence as major barrier (ERS Research and Consultancy, 2013; Farenden *et al.*, 2015; Whitelaw *et al.*, 2017). Lack of shared understanding across partners, led to a mismatch of expectations, tensions, and disappointment during the implementation process of SP in Brighton and Hove (Farenden *et al.*, 2015). For example, a mismatch in expectations of change was identified between the health and community organisations, which resulted in service provider frustration and lack of motivation. It was understood that in the health sector the implementation of change requires careful development and time, whereas community organisations, with a small part-time staff team, were expected to implement changes immediately (Farenden *et al.*, 2015). A lack of partnership agreements (outlining the scope of the programme, the role, and what can be expected from each partner), may explain the lack of shared understanding of roles and responsibilities among partners in the Brighton and Hove programme (Farenden *et al.*, 2015). Moreover, the lack of a service level agreement (including the scope of the service, model, data requirements, arrangements, and details of governance structure) meant that the agreed model and data requirements changed at intervals, resulting in increased staffing costs for service management, navigator coordination, and data monitoring (Farenden *et al.*, 2015).

GPs felt that a general lack of awareness about SP in the society makes it difficult to start a conversation about it in a time-limited consultation (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012). A publicity campaign educating the community about SP was an effective way to increase awareness about SP (Friedli, Themessl-huber and Butchart, 2012). Working in collaboration with the practice manager to promote SP awareness among patients, was also perceived as beneficial. It allowed the information about SP to go on to TV screens in practices to inform patients and to be included in the practice newsletter, leaflets in the

waiting room, and on the practice website (Age UK and Age concern, no date; Friedli, Themessl-huber and Butchart, 2012; The Health Foundation, 2015). The study by Brandling *et al.* (2011) found that some service users attended the first appointment with the navigator without understanding SP and why they were referred to it. Some service users reported to have difficulties in remembering what the GP said during the consultation (Brandling *et al.*, 2011). In addition, navigators reported that they did not always feel able to communicate SP in a way that it is relevant to service users (Brandling *et al.*, 2011). Not understanding what SP is about and why one was referred, resulted in wrong patient expectations towards SP (Brandling *et al.*, 2011). This might negatively affect the levels of service user adherence, engagement, and outcomes, hindering the implementation and delivery of SP programmes (Brandling *et al.*, 2011).

Communication and relationships

It appeared that communication and relationships are two inter-linked concepts; effective communication is required to build good relationships, and good relationships are essential to communicate well. Both were considered as critical enablers to the implementation of SP (Brandling *et al.*, 2011; Farenden *et al.*, 2015; The Health Foundation, 2015; Skivington *et al.*, 2018). It was perceived important that all involved partners and stakeholders give time and are willing to create new relationships based on reciprocity and trust (Farenden *et al.*, 2015). Shared perspectives and attitudes, as well as the principles of ‘mutual trust, understanding, and respect’ (Farenden *et al.*, 2015, p. 38) enhanced effective partnership working across organisations and sectors (Farenden *et al.*, 2015).

Building relationships with GP practices and continuous communication between navigators and practice staff (e.g. GPs and practice managers) were regarded as important elements in the success of joint working (Age UK and Age concern, no date; Farenden *et al.*, 2015). Several studies have found that direct feedback on service users’ journeys and outcomes to GPs, either via the navigator during regular meetings or a short periodic report, enhanced the understanding of their patients’ process and motivation to refer to SP (Age UK and Age concern, no date; ERS Research and Consultancy, 2013; Farenden *et al.*, 2015; The Health Foundation, 2015; Whitelaw *et al.*, 2017). In addition, structured contact and regular feedback and communication between navigators, referrers, and the practice staff, served as a reminder of SP and encouraged a higher number and greater appropriateness of referrals (ERS Research and Consultancy, 2013; Farenden *et al.*, 2015). However, the lack of established communication pathways (i.e. via referral forms or a shared IT platform), hindered the communication and information sharing between front-line providers along the SP pathway (Dayson, Bashir and Pearson, 2013; The Health Foundation, 2015). Due to the lack of

communication, service providers were not informed about the patient needs (e.g. mobility issues, medical conditions, or mental health issues), which led to the provision of insufficient support to service users (Dayson, Bashir and Pearson, 2013; The Health Foundation, 2015). A shared IT system for front-line providers was identified as a facilitator to effective communication between primary care staff, navigators, and third sector organisations in one study (Whitelaw *et al.*, 2017). In addition to improved communication, the shared IT system allowed effective transfer of patient data between primary care staff and navigators, information sharing, and the possibility to monitor data and referrals (Whitelaw *et al.*, 2017).

The study by Skivington *et al.* (2018) found that navigators and representatives of the community organisations found it difficult to build sustainable relationships between organisations, independently of the specific individuals involved. They emphasised that relationships are exclusively built on the individual level, rather than on the organisational one (Skivington *et al.*, 2018). Community organisation representatives identified the lack of relationships on an organisational level as a major barrier to programme sustainability, as they did not expect their collaborative relationship with primary care practices to continue once the navigator left the programme (Skivington *et al.*, 2018).

Human resources

Navigator's role

The role of navigators is to engage, motivate, and support service users to meet their psychosocial needs. Being familiar with the services and activities in the third sector, good listening skills, interpersonal qualities, and effective communication with all stakeholders (i.e. managers, practice team members, service providers in the third sector, co-workers, and service users) were viewed as important navigator skills facilitating successful implementation and outcomes (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013; Farenden *et al.*, 2015; The Health Foundation, 2015; Skivington *et al.*, 2018). Most navigators have advanced social skills, and a background career in related fields of healthcare, social services, counselling, and teaching (Brandling *et al.*, 2011; Farenden *et al.*, 2015). Navigator training to support growth and development, relationship building, and problem solving for complex cases was identified as important for successful implementation, delivery, and sustainability of SP programmes (Friedli, Themessl-huber and Butchart, 2012; Farenden *et al.*, 2015)

Whilst volunteer navigators are highly skilled individuals with a wealth of experiences, operating a SP programme with volunteers as navigators required a higher level of flexibility than is necessary with paid staff (Farenden *et al.*, 2015). Using volunteers as navigators also

delayed the implementation of SP, as it took longer to implement changes to processes and volunteers required more intensive support than what would be expected of paid staff (Farenden *et al.*, 2015). For example, it took several weeks until changes in the recording system were adopted by the whole navigator team in the Brighton and Hove SP programme (Farenden *et al.*, 2015). There were also inconsistencies in record keeping, which resulted in extra work, as staff needed to phone volunteers up for clarifications (Farenden *et al.*, 2015). Furthermore, volunteer turnover is generally higher than paid staff turnover, with an average of one in three volunteers leaving the navigator role within a year (Farenden *et al.*, 2015).

Staff turnover

There is a risk that in markets with high employee mobility, staff who are often employed via temporary contracts to support SP pilots (e.g. navigators or project managers), may seek alternative more stable employment (Dayson, Bashir and Pearson, 2013; Farenden *et al.*, 2015). This is particularly true if the future or prospect of their roles in a pilot programme remains unclear (Dayson, Bashir and Pearson, 2013; Farenden *et al.*, 2015). The continuity of the SP programme in City and Hackney was affected negatively when two of the navigators left the SP project after the first year (The Health Foundation, 2015). The CCG senior project lead officer left the SP project in Newcastle, which resulted in the loss of links to key personnel within the CCG and GP practices, negatively affecting the implementation of the programme (ERS Research and Consultancy, 2013).

Referrals to social prescribing

Two studies suggest that a brief, simple, and easy to complete referral form encourages referrals to SP (Age UK and Age concern, no date; Farenden *et al.*, 2015). Furthermore, to encourage referrals, the referral system for SP should fit with existing referral systems in general practices (Age UK and Age concern, no date; Brandling *et al.*, 2011). Two studies found that GPs found it difficult to provide consistent and fulsome information about SP to patients in a time-limited consultation (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012). GPs believed that training on how to explain SP to patients, for example on words and examples they can use, would facilitate and encourage referrals to SP (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012). As the SP pathway starts with a patient referral from general practice staff, low or no practice staff engagement was identified as a major barrier to implementation (Farenden *et al.*, 2015). GPs who participated in the Maryfield SP programme, felt that SP did not sit well with the traditional biomedical model of health to which they are used to work in (Friedli, Themessl-huber and Butchart, 2012). To create greater scope for addressing the wider determinants of health and to open up discussion about SP, health professionals needed to change their consultation style (Friedli, Themessl-

huber and Butchart, 2012). Furthermore, health professionals' attitudes needed to change towards a whole person approach, i.e. considering social, psychological, and environmental determinants of health, instead of focusing on medical needs only (Friedli, Themessl-huber and Butchart, 2012; Whitelaw *et al.*, 2017). For example, following the biomedical model of health, depressive symptoms, appetite and sleeping issues may naturally lead to the prescription of anti-depressants and sleeping tablets (Friedli, Themessl-huber and Butchart, 2012). To introduce and refer patients to SP, health professionals had to move away from the biomedical model towards a biopsychosocial model of health, considering alternatives to medical interventions (Friedli, Themessl-huber and Butchart, 2012). GPs who engaged with SP and referred patients to navigators tended to have a higher level of trust in the navigators than those GPs who did not engage (Farenden *et al.*, 2015). In addition to a lack of trust, GPs listed lack of time within busy consultations, lack of confidence to explore the social determinants of health, forgetting about the availability of SP, and scepticism about patients effectively attending activities in the third sector as barriers to engaging with- and referring patients to SP (Brandling *et al.*, 2011; The Health Foundation, 2015). Listed strategies that encouraged and maintained regular referrals include feedback letters from navigators to referrers, regular education events and training sessions, encouraging navigator attendance at surgery staff meetings, and having information stalls within practice reception areas (The Health Foundation, 2015). Moreover, the study by Whitelaw *et al.* (2017) found that it was important for health professionals (referrers) to know that they could confidentially refer patients into quality assured (i.e. safe, reliable, high-quality) non-NHS services. Without assured confidentiality and quality, health professionals resisted to referring patients to SP, a non-NHS service, as they felt responsible for their referrals (Whitelaw *et al.*, 2017).

A 'champion' within primary care teams; someone who reminded colleagues of the benefits and value of SP and provided sustained motivation and support, appeared critical to promote on-going referrals and therefore for the success in many surgeries (Age UK and Age concern, no date; Farenden *et al.*, 2015).

Health professionals faced the challenge to proactively identify suitable patients for SP (Brandling *et al.*, 2011; ERS Research and Consultancy, 2013; Farenden *et al.*, 2015). Large numbers of inappropriate referrals (e.g. housebound patients, patients with very complex needs, or patients with reduced mobility) were identified as a barrier to implementation and delivery. Inappropriate referrals increased the bureaucratic work for navigators and referrers, required additional time (staff hours) to identify inappropriate referrals or to deal with the complex needs of patients, resulting in additional workload and costs (Farenden *et al.*, 2015).

Patient uptake and adherence to SP

No or low patient uptake and adherence was identified as a major barrier to implementation (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013). GPs felt that engaging patients is difficult because SP is a new way of working in general practice, which is difficult to explain, and not always understood by their patients (Friedli, Themessl-huber and Butchart, 2012). Reported reasons for patient non-uptake were lack of interest in SP, scepticism around its potential benefit, and patient entrenchment in medical solutions (i.e. patients expected medicalised care from primary care) (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; Whitelaw *et al.*, 2017). In addition, low motivation to move from contemplation to action, concerns that SP represent a threat to welfare entitlement, fear of stigmatisation, and fear of being labelled as depressed on the WEMWBS (used by navigators as a tool to evaluate service outcomes), were identified as key barriers to patient uptake and adherence to SP (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012). The study by Brandling *et al.* (2011) found that service users were unable to attend prescribed services in the third sector (adherence) because they lost confidence or due to financial constraints (e.g. limited funds to dress up appropriately, buy refreshments, or pay for public transport).

Third sector resources

The successful implementation of SP services was contingent on the resources available in the local community and voluntary sector. In order to meet the individual needs of referred patients, a wide range of good quality third sector based services and activities needed to be available locally (Friedli, Themessl-huber and Butchart, 2012; Farenden *et al.*, 2015; Whitelaw *et al.*, 2017). Service users were more likely to engage in prescribed services and activities when service provider organisations were located within easy reach of the service user's home and good public transport is available (ERS Research and Consultancy, 2013).

Challenges for implementing and sustaining SP programmes were apparent with the context of austerity (Whitelaw *et al.*, 2017; Skivington *et al.*, 2018). There was a risk that available services and activities in the third sector may be cut below the level of service users' needs (Farenden *et al.*, 2015). Findings from the SP pilot in Brighton and Hove suggest that the risk was especially high to the most commonly referred-to services, which are of limited availability and already received, or are at immediate risk, of funding cuts (Farenden *et al.*, 2015). Examples for such services include social and practical support for older people, befriending services, and welfare benefits advice and advocacy (Farenden *et al.*, 2015). Reduced financial resources led to restricted capacity of community organisations to accommodate the increased level of referrals from navigators without extra resources to

manage them (Skivington *et al.*, 2018). Navigators have reported difficulties to refer service users to appropriate services and activities because of reductions in scope and longer waiting lists for services provided by third sector organisations (Friedli, Themessl-huber and Butchart, 2012; Farenden *et al.*, 2015). Studies also found that the engagement of community and voluntary sector organisations in SP was challenging, which was viewed as a barrier to implementation and sustainability of SP (The Health Foundation, 2015; Whitelaw *et al.*, 2017). Organisations refused to participate in SP, due to little direct funding to accommodate the increased level of referrals from navigators (The Health Foundation, 2015; Whitelaw *et al.*, 2017). Thus, austerity was viewed as a major challenge to collaborative working between SP and third sector organisations, which reported to be uncertain about their future (Skivington *et al.*, 2018).

7.2.4 Secondary outcomes

This section provides the findings from the narrative analysis to identify service user outcomes. The following themes were identified: Mental health and wellbeing, physical health and wellbeing, general health and wellbeing, health-related behaviours, self-concepts and emotions, new skills and opportunities, social interactions, and employment and day-to-day functioning. Included qualitative studies used interviews and focus groups to explore service user outcomes. A wide range of tools was used in included quantitative studies to measure service user outcomes. Table 33 in Appendix 2 summarises the 24 quantitative tools used in the included studies to measure service user outcomes.

Mental health and wellbeing

Several qualitative studies found that SP helped service users to improve their self-management of mental health (e.g. steps to deal with anxiety or prevent the downward spiral to severe depression) and their mental wellbeing (White, Kinsella and South, 2010; ERS Research and Consultancy, 2013; Kimberlee *et al.*, 2014; The Health Foundation, 2015; Dayson *et al.*, 2016; Moffatt *et al.*, 2017).

The WEMWBS is a frequently used tool to assess a change in mental wellbeing of service users of SP. Five uncontrolled before and after studies used the WEMWBS (Age UK and Age concern, no date; Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; Vogelpoel and Jarrold, 2014; Baines, 2015), and two uncontrolled before and after studies used the SWEMWBS (ERS Research and Consultancy, 2013; Wigfield *et al.*, 2015) to assess the change in mental wellbeing of service users. Statistical analysis of the pre- and post-WEMWBS scores of service users of SP in Maryfield (N=16), indicated a significant ($p<0.05$) improvement in mental wellbeing after participation (Friedli, Themessl-huber and

Butchart, 2012). In contrast, the study by Wigfield *et al.* (2015) did not find a statistically significant positive change in the SWEMWBS score (N=199). The other five studies did not conduct significance analyses due to small sample sizes, high dropout rates, and incomplete data, but reported a general trend towards improved mental wellbeing (i.e. an increase in the WEMWBS scores) (Age UK and Age concern, no date; Brandling *et al.*, 2011; ERS Research and Consultancy, 2013; Vogelpoel and Jarrold, 2014; Baines, 2015). The study by Brandling *et al.* (2011) reported the standard deviation and range of the data, which showed large variability of WEMWBS score within the sample at different time points (Baseline: SD: 9.68, Range: 22-62, Follow-up 1: SD: 8.11, Range: 29-57, Follow-up 2: SD: 14.37, Range: 25-63) (Brandling *et al.*, 2011).

One controlled before and after study (The Health Foundation, 2015) and one RCT (Grant *et al.*, 2000) used the HADS to assess a change in mental health of service users. The controlled before and after study by The Health Foundation (2015) found no statistical significant difference in anxiety and depression scores between baseline and eight months after referral in the intervention and control group. The RCT by Grant *et al.* (2000) found a significant difference in anxiety ($p=0.002$) and a non-significant difference in depression ($p=0.116$) between mean scores on the HADS for the intervention and control group, averaged across the two follow up periods and adjusted for baseline scores (Grant *et al.*, 2000). The intervention group showed significantly greater improvement in anxiety than the control group, whereas no difference was detected in depression (Grant *et al.*, 2000).

One uncontrolled before and after study used the General Health Questionnaire-12 (GHQ-12) to assess a change in the number of patients with mental health problems before and after participating in SP (Grayer *et al.*, 2008). Results showed that at baseline 57 participating patients (83%) were classified as having a mental health problem, reducing to 36 (52%) post intervention (difference 31%, 95% CI: 17%-44%) (Grayer *et al.*, 2008).

The uncontrolled before and after study by Kimberlee (2014) used the 9-item Patient Health Questionnaire (PHQ9) scale for depression and the 7-item Generalised Anxiety Disorder (GAD7) Scale for anxiety at baseline and three months follow-up to assess changes in mental health of service users. There was a statistically significant decrease in PHQ9 depression scores and GAD7 anxiety scores (indicating improvements) from baseline to three months follow-up ($p<0.001$ 95% CI: 8.2-11.69 and $p<0.001$ 95% CI: 6.9-9.4 accordingly) (Kimberlee *et al.*, 2014).

Physical health and wellbeing

Health professionals and service users reported that SP positively impacted on the physical health of participants (White, Kinsella and South, 2010; ERS Research and Consultancy, 2013; Kimberlee *et al.*, 2014; Dayson *et al.*, 2016; Moffatt *et al.*, 2017). Improvements in blood pressure, weight loss, reduced cholesterol and sugar levels, reduction in alcohol and drug consumption, and improved health related behaviours (including reduced intake of unhealthy foods and increased physical activity) were listed outcomes associated with improved physical health (White, Kinsella and South, 2010; ERS Research and Consultancy, 2013; Kimberlee *et al.*, 2014; Dayson *et al.*, 2016; Moffatt *et al.*, 2017).

The RCT by Grant *et al.* (2000) found a statistically significant difference in the COOP/WONCA functional health assessment chart for pain between the intervention and control group ($p=0.005$, 95% CI: -0.8 to -0.1). The intervention group showed greater improvement on the COOP/WONCA functional health assessment charts for pain (i.e. reduced pain) compared to the control group. However, no significant difference was detected on the COOP/WONCA functional health assessment charts for physical fitness between the control and the intervention group ($p=0.098$, 95% CI: -0.6 to 0.05) (Grant *et al.*, 2000).

General health and wellbeing

Service users reported that SP contributed to improvements in their general health, wellbeing, and quality of life (Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013; Dayson *et al.*, 2016). The evaluation of the SP programme in Brighton and Hove found that three to six months after completing the programme, 84% (N=84) of the interviewed service users experienced improvements in their sense of wellbeing (Farenden *et al.*, 2015). One uncontrolled before and after study found a statistically significant improvement on each of the four items of the ONS wellbeing indicator scale at three months follow-up (satisfaction with life $p<0.001$, feeling happy $p<0.001$, feeling anxious $p<0.001$, and feeling of doing worthwhile things in life $p<0.05$) (Kimberlee *et al.*, 2014).

As part of the evaluation of the Rotherham SP programme, the progress of service users towards self-management was measured with a wellbeing measurement tool developed for the SP service in Rotherham (Dayson *et al.*, 2016). Service users completed the tool at baseline (n=1843) and three to four months follow up (n=1068) (Dayson *et al.*, 2016). Overall, 82% (n=876) of service users who had been followed up experienced a positive change on at least one of the eight outcome measures of the wellbeing tool (Dayson *et al.*, 2016). The progress made against each outcome measure for all service users and for low-scoring service users (scores from 0 to 2) is as follows:

- Feeling positive: 35% made progress, 65% of low-scoring service users
- Lifestyle: 26% made progress, 59% of low-scoring service users
- Looking after yourself: 23% made progress, 57% of low-scoring service users
- Managing symptoms: 23% made progress, 52% of low-scoring service users
- Work, volunteering and other activities: 46% made progress, 57% of low-scoring service users
- Money: 28% made progress, 71% of low-scoring service users
- Where you live: 24% made progress, 68% of low-scoring service users
- Family and friends: 19% made progress, 63% of low-scoring service users

Statistical testing found that the proportion of service users moving from low baseline scores (0-2) to a high score (3-5) was statistically significant (Dayson *et al.*, 2016).

There was no statistically significant difference in general health ($p=0.838$) and wellbeing ($p=0.714$) between service users of the SP programme in City and Hackney (intervention group) and the control group (The Health Foundation, 2015). In addition, a statistically significant change in health related quality of life in both the intervention and control group was found, which indicates that the positive change cannot be associated with SP (The Health Foundation, 2015). Results remained the same after controlling for age, gender, ethnicity, living arrangements, and work status (The Health Foundation, 2015).

To evaluate changes in the general wellbeing of service users of the SP programme in Keynsham, adapted Measure Yourself Medical Outcome Profile (MYMOP) scores were recorded at three time points (baseline, between 3-6 months, between 6-12 months) during their participation in the programme (Brandling *et al.*, 2011). At baseline, 64 service users completed the MYMOP, however, loss of follow-up was high, resulting in only 18 service users completing the MYMOP at time point 2, and 12 service users at time point 3 (Brandling *et al.*, 2011). Analysis found that the mean MYMOP scores did reduce, indicating that service users may be in better general health and wellbeing at the end of the intervention than at the start (Brandling *et al.*, 2011).

In the study by Grant *et al.* (2000), the intervention group showed a greater improvement on the COOP/WONCA functional health assessment charts for change in health compared to two weeks ago ($p=0.030$, 95% CI: -0.6 to -0.03) and for overall health ($p=0.003$, 95% CI: -0.7 to -0.1), than the control group (Grant *et al.*, 2000). Moreover, the intervention group showed a statistically significant greater improvement on the delighted-terrible faces scale ($p=0.006$,

95% CI: -0.9 to -0.1), measuring perceived quality of life, than the control group (Grant *et al.*, 2000).

To measure the effect of SP on the global distress of service users, the Clinical Outcomes in Routine Evaluation-Outcomes Measure (CORE-OM) was used in one study (Grayer *et al.*, 2008). Statistical testing showed that a smaller proportion of patients were classified as cases at follow up (n= 50) than at baseline (n=63) (Grayer *et al.*, 2008).

To assess whether medication prescription changed with SP activities the number of repeat prescriptions at baseline and six to 12 months after referral were compared in one study (Loftus, McCauley and McCarron, 2017) and six months before and after referral in another study (Carnes *et al.*, 2017). There were no statistically significant changes in the number of prescribed medications at baseline compared to six to 12 months and between six months before and after the referral to SP (p=0.084 and p=0.156 accordingly) (Carnes *et al.*, 2017; Loftus, McCauley and McCarron, 2017). Thus, the number of medications prescribed for those referred to SP did not change significantly in both studies.

Health-related behaviours

Service users reported several health-related behaviour changes since the SP referral, including increased physical activity levels, healthier diets, reduced alcohol and drug consumption, and making healthier lifestyle choices on a daily basis (White, Kinsella and South, 2010; Kimberlee *et al.*, 2014; Moffatt *et al.*, 2017). Service users and health professionals believed that health related behaviour changes were triggered by the experienced health and wellbeing improvements (outlined above) (White, Kinsella and South, 2010; Kimberlee *et al.*, 2014; Moffatt *et al.*, 2017). Qualitative studies found that SP helped service users to identify their needs and take actions to improve their health and wellbeing (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; Farenden *et al.*, 2015). Service users identified one-to-one meetings with a navigator and the establishment of a supportive relationship based on trust, as major enablers to behaviour change (Friedli, Themessl-huber and Butchart, 2012; Farenden *et al.*, 2015). The study by Moffat *et al.* (2017) identified continuous and need driven support and motivation from navigators as a major facilitator to uptake and continuous engagement with referred services (adherence). Moreover, service users reported that they built their self-reliance, self-confidence, and independence during the work with navigators, so that they felt ready to engage with referred services in the third sector (Moffatt *et al.*, 2017). Interestingly, two studies found that contact with navigators, and their help to identify non-medical needs, was enough for some service users to take actions to improve their health-related behaviours (i.e., they did not need to

complete the whole SP pathway) (Brandling *et al.*, 2011; ERS Research and Consultancy, 2013).

The study by Wigfield *et al.* (2015) constantly reported a statistically significant positive change (the significance level was not defined in the report) in attitude to physical activity and weekly duration of walking and exercises that make respondents breathe harder, at the end of the SP programme (compared to baseline measures). However, reported p-values showed a non-significant change in attitude ($p=0.10$) at a 5% significance level, and are unclearly reported ($p=>0.01$) for changes in exercises that make service users breathing hard (Wigfield *et al.*, 2015). No statistically significant changes were observed in attitudes to healthy eating ($p=0.164$) and fruit and vegetable consumption ($p=0.175$) at the end of the intervention (compared to the baseline measures) (Wigfield *et al.*, 2015).

One uncontrolled before and after study used the IPAQ to compare physical activity levels at baseline and three months after referral (Kimberlee *et al.*, 2014). The study found a statistically significant increase in the frequency of weekly walking ($p<0.004$) and moderate exercise ($p=0.001$) (Kimberlee *et al.*, 2014) post-intervention. No statistically significant change was observed in the frequency of weekly vigorous physical activities ($p=0.127$) at the end of the intervention (Kimberlee *et al.*, 2014).

Self-concepts and emotions

Qualitative research across multiple studies found that participating in SP improved the self-esteem, self-value, and hope of service users and made them feel useful and worthwhile (Brandling *et al.*, 2011; ERS Research and Consultancy, 2013; Vogelpoel and Jarrold, 2014; Baines, 2015; The Health Foundation, 2015; Dayson *et al.*, 2016). Another commonly reported outcome for service users is an improvement in self-confidence (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013; Kimberlee *et al.*, 2014; Vogelpoel and Jarrold, 2014; Dayson *et al.*, 2016; Moffatt *et al.*, 2017). Qualitative findings showed that SP has the potential to develop and enhance self-confidence and independence of service users, so that they feel able to travel with public transport, leave their house, get involved in new activities in their community, take control over their health/live, and to manage their conditions (White, Kinsella and South, 2010; Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; ERS Research and Consultancy, 2013; Farenden *et al.*, 2015; The Health Foundation, 2015; Dayson *et al.*, 2016). Confidence to participate in group discussions and working with others is another reported outcome for service users with sensory impairments (Vogelpoel and Jarrold, 2014). However, one service user of the SP programme in Newcastle reported feeling less confident after

participating in SP, as a result of not experiencing the expected health improvements (ERS Research and Consultancy, 2013).

One uncontrolled before and after study used a confidence scale (tool not specified) to assess the change in self-confidence of service users (ERS Research and Consultancy, 2013). Inconsistent and incomplete data collection resulted in significant gaps in the data, preventing clear trends emerging, statistical analysis, and thus drawing firm conclusions (ERS Research and Consultancy, 2013). However, a trend indicating an increase in confidence to manage long-term conditions for those service users who completed the confidence scale at both time points (N=7) were observed (ERS Research and Consultancy, 2013).

New skills and opportunities

Service users reported that they found new hobbies through SP, as they learned new skills, for example how to play sports, use gym equipment, and art techniques, or revived existing skills (Kimberlee *et al.*, 2014; Vogelpoel and Jarrold, 2014; Dayson *et al.*, 2016; Moffatt *et al.*, 2017). Attending SP services also increased service users' awareness about other local activities and, therefore, opened up new opportunities to get involved with activities in their local communities (Friedli, Themessl-huber and Butchart, 2012).

Social interactions

Social isolation and loneliness were commonly related to poor mental health and long-term conditions preventing social interactions, free time activities, and engagement in the community (Vogelpoel and Jarrold, 2014; Farenden *et al.*, 2015; Dayson *et al.*, 2016). Results of the evaluation of the SP programme in Brighton and Hove showed that 60% of service users who were socially isolated (total number of socially isolated service users not provided) felt more satisfied with the amount of time they spend with others as a result of participating in SP (Farenden *et al.*, 2015). Offering opportunities for activities, which allowed people to establish social links, new friendships, a sense of belonging, group cohesion, and to socialise and meet people in the community, reduced social isolation (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; Kimberlee *et al.*, 2014; Vogelpoel and Jarrold, 2014; The Health Foundation, 2015; Dayson *et al.*, 2016; Moffatt *et al.*, 2017). Service users also reported that they felt the mood to reconnect to old friends after participating in SP (Brandling *et al.*, 2011).

One uncontrolled before and after study used the Friendship scale for isolation to assess the change in social isolation from baseline to three months follow-up (Kimberlee *et al.*, 2014). There was a statistically significant increase in the Friendship scale scores ($p < 0.001$)

indicating reduced social isolation at the end of the intervention (compared to baseline scores) (Kimberlee *et al.*, 2014). However, the RCT by Grant *et al.* (2000) found no significant difference in perceived social support on the Duke-UNC functional social support scale (Confidant support $p=0.221$, 95% CI: -2.4-0.6, Affective support $p=0.594$, 95% CI: -1.2-0.7), and on the COOP/WONCA functional health assessment charts for social activities ($p=0.195$, 95% CI: -0.6-0.1), between the intervention and control group (Grant *et al.*, 2000). The results maintained the same after controlling for potential confounders (Grant *et al.*, 2000). The uncontrolled before and after study by Wigfield *et al.* (2015) found no statistical significant difference in any of the four indicators used to measure loneliness and isolation post intervention (compared to baseline scores).

Employment and day-to-day functioning

To address wider economic and social issues, navigators provided advice and information, or made referrals into services to address debt, welfare, employment, and housing issues (White, Kinsella and South, 2010; Kimberlee *et al.*, 2014; Baines, 2015; Moffatt *et al.*, 2017). Numerous qualitative studies found that SP helped service users to find a job or to go back to work after illness or accident, through employment assistance (e.g. curriculum vitae writing, motivation, and support from navigators and referred services (White, Kinsella and South, 2010; Kimberlee *et al.*, 2014; The Health Foundation, 2015; Carnes *et al.*, 2017; Moffatt *et al.*, 2017). Another important aspect of SP services was to help service users to understand their situation and to access a range of welfare benefits they are entitled to but often were not aware of (Baines, 2015; Dayson *et al.*, 2016; Moffatt *et al.*, 2017). Moreover, navigators took practical action to solve daily problems and worries of service users (e.g. getting a wheel chair for a service user's disabled child) (White, Kinsella and South, 2010). Service users reported that due to SP they felt able to better cope with day-to-day activities (Dayson *et al.*, 2016).

Two uncontrolled before and after studies used the Work and Social Adjustment Scale (WSAS) to measure impaired functioning (Grayer *et al.*, 2008; Friedli, Themessl-huber and Butchart, 2012). The study by Grayer *et al.* (2008) and Friedli *et al.* (2012) found a significant decrease in the WSAS score post intervention (Difference 3.69, 95% CI: 1.54-5.84 and $p<0.05$ accordingly), indicating a reduction in impaired functioning (i.e. an improvement). The RCT by Grant *et al.* (2000) found that the intervention group, in contrast to the control group, showed a significant improvement on the COOP/WONCA functional health assessment charts for being able to perform daily activities ($p=0.001$, 95% CI: -0.8- (-0.2)), post intervention (Grant *et al.*, 2000). However, the study by the Health Foundation (2015) found no statistically significant change in 'positive and active engagement in life' between

the intervention and control group ($p=0.905$), as the results remained stable after controlling for potential confounders (The Health Foundation, 2015). Engagement was measured on a scale from 5 (poorly isolated) to 20 (highly integrated), however, the tool is not specified or described in more detail in the evaluation report (The Health Foundation, 2015).

7.2.5 Summary of findings

Primary outcomes

There is evidence that operational processes, such as the approach to implementation (phased roll out vs. go live dates), programme adaptability to respond to unforeseen challenges, on-going support and supervision for providers, and early involvement of stakeholders in the development of SP programmes, influenced the implementation of SP programmes in the UK. Navigator-ready surgeries were identified as critical for successful implementation and delivery of SP programmes in this review. Shared knowledge and understanding among stakeholders (including patients) is crucial for effective partnership working and therefore, the successful implementation and delivery of SP. Service level and partnership agreements were identified as useful to ensure shared understanding and prevent tensions and conflicts between stakeholders on a long-term. In addition, good communication and relationships between partners within and across organisations were identified as important facilitators. Ensuring that there is enough time to build new relationships and integrative teams is necessary to build relationships based on trust and reciprocity. On-going communication between navigators and GPs (referrers) was also identified as a reminder for SP, boosting referrals. However, the review found that the focus on relationship building is unevenly weighted towards relationships between individuals (e.g. providers and navigators), neglecting meso-level strategies, such as relationship building on an organisational level, independent from specific individuals. Focusing on relationships between individuals only was identified as a risk for the sustainability of SP programmes. The navigators were identified as a key stakeholder group, influencing the implementation process, as well as patient uptake and adherence to SP. Effective communication and good listening skills, as well as interpersonal qualities were identified as key characteristics of navigators. A simple and short referral process for referrers (GPs) was identified as a facilitator to implementation. This review found that GPs may find it difficult to start a conversation of SP, as it is beyond the routine practice, which may hinder referrals to SP, and in turn its implementation. Providing training and support to GPs on how to explain SP to patients, was identified as a helpful mechanism to boost referrals to SP. Lastly, high quality services provided in the third sector are a key element of SP programmes. The review found that financial pressures and funding cuts made it difficult to engage third sector organisations in SP, and thus, may hinder the implementation of SP on a long-term. In addition, high demands for third sector services resulted in long waiting lists for SP service

users, delaying the delivery, and intended outcomes of SP. The review has also found that the accessibility of services in the third sector, low confidence, and financial constraints were identified as barriers to service user adherence to SP.

Secondary outcomes

There is evidence from qualitative studies that service users experienced improvements in their mental, physical, and general health and wellbeing, as well as health-related behaviours, after participating in SP. The following factors were identified as major facilitators to patient uptake and engagement with SP: On-going and need driven support and motivation from navigators and the development of trust relationships with the navigator. Understanding the needs and being able to take actions to meet these needs to improve one's health and wellbeing, were identified as key facilitators to behaviour change. Quantitative studies used different tools to assess a change in mental, physical, and general health and wellbeing, and found mixed results. Self-concepts and emotions were explored mainly by qualitative studies, and with one reported exception, improved after participating in SP. One study used a quantitative confidence scale (tool not specified), and found a trend towards general improvement in confidence to manage long-term conditions. Qualitative studies found that SP allowed service users to learn new skills or revive skills. Through engagement with SP services, they also learned about more opportunities to get involved in their local community. Although qualitative studies consistently found that SP reduced social isolation and loneliness, quantitative studies found mixed results. Lastly, there is strong evidence from qualitative studies that SP can improve practical, housing, employment, and welfare issues, through advice, guidance, information, and provided support. Three quantitative studies found statistically significant improvements in daily functioning after participating in SP, whereas one found no significant change in positive and active engagement in life post-intervention, between the intervention and control group. The quantitative findings are summarised in Appendix 2.

7.3 Chapter summary

This chapter presented the findings of the systematic literature review (Objective 1). The review found that the quality of most evaluations of SP is weak, due to methodological challenges or poor and not transparent reporting. The fact that most of the included studies were published or made available in the last eight years, indicate that SP is a relatively new concept in the UK. The review identified a wide range of facilitators and barriers (primary outcomes) to the implementation of SP programmes, which tend to be interrelated. Moreover, the review found that the evidence base for service user outcomes (secondary outcomes) is

mixed, and therefore no conclusion about the effectiveness of service user outcomes can be drawn at this stage.

8 Chapter 8: Qualitative findings: Implementation, uptake, adherence, and outcomes of the Luton social prescribing programme

8.1 Introduction

This chapter presents the findings of the qualitative research, which addressed:

- Objective 2: To identify the factors that facilitate and hinder the implementation of the Luton SP programme (section 8.2)
- Objective 3: To explore the factors that affect patient uptake and service user adherence to the Luton SP programme (section 8.3)
- Objective 4: To assess and explore service user outcomes of the Luton SP programme (section 8.4)

Each section starts with an overview of the characteristics of participants and then presents the findings by themes.

8.2 Objective 2: Facilitators and barriers to the implementation of the Luton social prescribing programme

8.2.1 Participants

General practitioners

In total, three GPs, each from different participating surgeries were interviewed. The original plan was to recruit at least one GP from each of the four participating practices, hence to interview four GPs. However, besides several attempts from the navigators, CCG members, programme manager, and myself it was not possible to recruit any GPs from one of the four participating practices. This could be attributed to several contextual factors. Firstly, due to structural changes, general practice staff experienced an exceptionally high workload to register new patients during the recruitment and initial interview period of this study. Secondly, the practice manager retired, which meant that supporting the recruitment of GPs for my study was not a priority at that time. Thirdly, at the time the workload should have reduced (February 2017), the navigator working in this practice resigned from the pilot. This left the surgery without a navigator, and therefore SP, for a while. The characteristics of the three participating GPs are summarised in Table 10.

Table 10: GP demographics (N=3)

GPs N = 3	
Age, years	
40-49	1
50-59	2
Sex	
Female	1
Male	2
Working hours	
Full time	2
Part time	1
Type of GP	
Salaried	1
Partner	2
Years of practising	
5-10	1
21-25	1
26-30	1

Navigators

During the recruitment and interview phase of this study, four navigators were working in the pilot. All four navigators were interviewed. It was originally planned to interview one of the first navigators who resigned from the pilot after six months and, therefore, was not employed as a navigator by the time interviews took place for this study. However, this was not possible, as she did not respond to relevant emails and phone calls. The characteristics of the four participating navigators are summarised in Table 11.

Table 11: Navigator demographics (N=4)

Navigators N=4	
Age, years	
20-29	2
40-49	2
Sex	
Female	3
Male	1
Ethnicity	
White British	3
Mixed White and Black	1
African	
Working hours	
Full time	4

Service providers

Six service providers in the third sector were interviewed. Five were accredited and one was planning to get accredited. Their characteristics (accreditation status, type of organisation, type of services, number of employees, and commissioning status) are outlined in Table 12. In the findings sections, service providers in the third sector are referred to as service providers.

Table 12: Service provider characteristics (N=6)

Interview number	Accreditation status	Type of organisation	Type of services	Number of employees	Commissioning status
Service provider 1	Accredited	Fitness club	Health and fitness	4	None-commissioned by Luton Borough Council
Service provider 2	Accredited	Private company	Alternative and holistic therapies	2	None-commissioned by Luton Borough Council
Service provider 3	Accredited	Charity	Health and wellbeing lunch clubs	14	Partly commissioned by Luton Borough Council
Service provider 4	Accredited	Community organisation	Healthy lifestyle service (e.g. stop smoking services, weight management)	25	Commissioned by Luton Borough Council
Service provider 5	Not-accredited	Charity	Support for vulnerable women and children	17	Non-commissioned by Luton Borough Council
Service provider 6	Accredited	Sport and leisure trust	Physical activity	200-250	Partly commissioned by Luton Borough Council

Managers and decision-makers

All of the nine initially considered managers and decision-makers, who were involved in the implementation of the SP pilot, were interviewed for this study. The interviewed participants had the following job roles:

- Better Together Project Manager (1)

- Community Development Manager taking SP business lead (1)
- Social Prescription Project Manager (1)
- Luton CCG members involved in the implementation of SP (2)
- Steering group members and key partners from the third sector (2)
- Commissioner (1)
- External consultant (1)

Given the relatively small size of the Luton SP programme, it is well known who, for example, the Better Together project manager, project manager, external consultant, etc. is. To prevent the identification of participants, the job roles were not aligned to a participation number. Independently from their specific job roles, participants in this stakeholder group will be referred to as Manager 1, Manager 2, Manager 3, etc. in the findings sections.

8.2.2 Findings

This section provides the findings from the analysis of the managers', service providers', navigators', and health professionals' views of factors that facilitated and hindered the implementation of the Luton SP programme. Due to the differences in stakeholders' experiences and views, barriers and facilitators were often two sides of the same coin (e.g. good communication/ poor communication). Therefore, as explained in the method section of this thesis (Chapter 6), the identified issues are presented here by theme, rather than attempting to identify barriers and facilitators separately. The following seven themes were identified: Operational processes, evaluation of the Luton SP programme, communication and relationships, shared knowledge and understanding, human resources, organisational readiness, and contextual factors.

Operational processes

Stakeholder engagement

Managers expressed the view that the involvement of primary care staff, potential service users, third sector organisations, and CCGs in the development of the Luton SP programme was an essential part of its early planning phase. To involve potential stakeholders in the programme's development, managers reported that they have organised various meetings, workshops, and presentations to discuss how a SP model for Luton could look like. A good understanding of stakeholders' perceived needs, benefits, risks, and challenges were emphasised as key enablers to implementation:

‘There were a whole range of meetings that we did (...) So we went to CCG engagement networks, we talked to patient groups, we talked to other people’s reference groups, we talked to the patient council, we also then had meetings with some of the organisations who are doing support around peoples’ mental health, we talked to mental health service users. We then talked to third sector groups, we had a number of events where we shared and did presentations for the third sector groups, and particularly in the pilot areas where people came in we made presentations. I went doing lots of presentations for people, this is the idea, what do you think? Is it right for Luton?’ (Manager 7)

Such events were believed to prepare and familiarise stakeholders with the concept of SP and to create favorable conditions facilitating the implementation:

‘in terms of creating the conditions for a successful pilot project (...) if we came along without that preparation, there would be no SP anymore. There would be potential resistance and barriers.’ (Manager 4)

The necessity to create favourable conditions for the implementation and to prepare potential stakeholders to prevent resistance to change, points to an environment in which the collaboration between the social and health sector is not a common practice.

Managers expressed the view that it is important to plan different events for different stakeholder groups, in order to promote awareness about SP and to address stakeholders’ backgrounds and specific interests. Furthermore, managers emphasised the importance of using appropriate language to explain the concepts and potential benefits of SP to different target groups, for example, primary care staff or third sector organisations:

‘There is no point in making it too complex, especially for *[service]* providers. I mean GPs have got the knowledge of that kind of things, but *[service]* providers, you need to really explain it in a language that they can understand it and what exactly is going to happen. And I think that was key as well, because they then got on board with that.’ (Manager 3)

In addition to appropriate language use, managers believed that inviting leading health professionals to make the case for SP, as ‘champions’, increased the interest of primary care staff in SP:

‘I think that we were able to bring in an external GP that is fairly accepted, Dr (Name of GP), to talk to other GPs around the benefits from a clinical perspective, and actually from a

practical perspective (...) You cannot beat having a clinician talking to clinicians. They [GPs] are much more accepting that than if it is management. So if you present the management case and the clinical case together you may be more likely to get their engagement, and I think this was a key catalyst for us as well.’ (Manager 8)

Multi-agency approach

The implementation of the SP programme in Luton was based on a multi-agency approach, as stakeholders across organisations and sectors were involved in the financing, planning, and implementation of the programme. There were two contrasting views among managers and navigators: some believed that a multi-agency approach facilitated the implementation process, whereas others believed it hindered it.

Some managers felt that a multi-agency approach was key to implementing the SP programme, as partners across sectors (e.g. the social sector, primary care sector, and local authorities) worked in collaboration, rather than having one organisation deciding and telling other organisations across sectors what to do:

‘I think it has been important that it has been like a multi-agency approach. So it is not only one organisation dictating what needs to happen (...) there are lots of different agencies that have been involved in how it is going to work. (...) So that is something that has been key to getting it [SP] started, I would say.’ (Manager 5)

Moreover, manager 5 emphasised that the benefit of a multi-agency approach is that the programme was planned in a more realistic way, as stakeholders across sectors were involved, or consulted, in planning and early decision-making stages:

‘everyone knows how their different areas work, rather than the programme lead guessing what might work within a GP surgery. The GP surgery can actually say, well we understand what you are saying, but realistically on the front-line than that is not going to work. So maybe you should do this, this, this, and this and then that would fit better. So it is that input that allowed it [SP] to evolve to fit what is needed.’ (Manager 5)

Managers who supported a multi-agency approach to implementation believed that the collaborative approach to programme implementation and management had the benefit of overcoming barriers and resistance to implementing change. In contrast to the managers who expressed the view that a multi-agency approach facilitated the implementation, other managers and the navigators perceived a multi-agency approach as a barrier to

implementation. Fragmentation of the programme was frequently mentioned as a consequence of the multi-agency approach:

‘fragmentation... the various elements of the project were split. So we are a health project but we also link in with the community through the Borough Council, but the navigators are both hosted by the two main community health organisations in the town, but the money comes from Public Health, which is overseen by CCG, which is project managed by the Borough Council. So it is very fragmented.’ (Navigator 2)

Furthermore, managers emphasised that the multi-agency approach resulted in a lack of ownership and responsibility for the programme. Managers and navigators also expressed frustrations about the amount of time it took to respond to issues and finalise work processes, which they attributed to the complicated and time consuming bureaucracy and decision-making processes among multiple organisations:

‘The (name of one organisation) and (name of another organisation) project lead at the time. They just had to continuously discuss it, take it to various boards, and get approval across them. So it would go to the health and wellbeing board, it would come to the CCG, clinical commissioning board, and so on, and then eventually it was resolved. It took long sometimes to respond to challenges.’ (Manager 9)

Although the NHS is investing in integrated social and health care with the Better Care Fund (which was mentioned as a key enabler to implementation), pooling budgets that historically had been used for either health or social care, resulted in increased bureaucracy and discussions among partners, which delayed implementation:

‘Obviously we have got financial barriers as well. We are talking about the health and clinical commissioning group and the local authority, we have got very separate budgets, so lot of the bureaucracy backwards and forwards, and particularly for the Better Care Fund and the Better Together Board around who is going to pay for what. It has been a sticking point, it is fair to say’ (Manager 8)

Managers and navigators blamed the multi-agency approach to programme management for poor leadership, resulting in the lack of progress. The absence of a programme manager who devoted time solely to implementing the pilot was perceived as major barrier to implementation, as sharing work and responsibilities resulted in fragmentation and higher error possibilities:

‘there was a missing piece if you like, somebody who is going to manage the finances, somebody who is going to work with the providers and that kind of fell to a mixture of everybody, myself and my office manager, the navigators, (name of a manager), and (name of another manager) all doing bits of it. That really was not the most effective way.’ (Manager 1)

Managers reported that they had to complete pilot related work on top of existing workloads and other day-to-day responsibilities. Due to a higher than expected workload and limited amount of time they could spend on the pilot activity, the completion of work processes was often delayed:

‘this [SP], again, is only one project in a huge range of projects, so we can only kind of put so much time into it. So it was all a bit kind of bitty really.’ (Manager 5)

Programme adaptability

Adaptability refers to the degree to which the SP programme could be adapted during the implementation process to eliminate unforeseen challenges. As the following quote illustrates, there were unforeseen challenges related to language barriers while the programme was implemented in one pilot area. One GP mentioned that most of his patients, who are suitable for the SP programme and needed it, couldn’t speak to a navigator without an interpreter:

‘Many people in this area, they are eastern European, they are Bangladeshi, Pakistani, and a majority of patients, who would need this SP, they do not speak English.’ (GP 2)

Responding to the service users’ needs and restructuring the delivery of the programme accordingly, i.e. arranging interpreters when needed, eliminated the unforeseen barrier and enabled the implementation of the programme in this particular pilot area:

‘So we discussed this (...) and they arranged interpreter services.’ (GP 2)

Most common of all frustrations experienced by service providers was the accreditation process, which third sector organisations had to complete before they could receive referrals from navigators. The accreditation process was externally managed and consisted of seven standards that service providers had to upload evidence for to an online platform. Managers, navigators, and service providers agreed that the accreditation process hindered service providers’ participation in the programme, which in turn hindered its implementation:

‘it hindered providers from coming on board, which acted as a barrier.’ (Manager 6)

‘we were told that there was a system (...) that we have to input information into. And it was awful, absolutely awful, I have never known anything like this in my life. I have pulled out at least three times.’ (Service provider 2)

The accreditation process was criticised for being too time consuming, complex, unclear, and poorly managed. Service providers emphasised that they did not understand the applied terms like ‘governance’ and missed support and guidance:

‘but we are not really educated (...) So when they start about governance and things like that, I still don’t know what this means.’ (Service provider 1)

To respond to the challenge, the accreditation system was amended and service providers’ preferences, such as submitting required documents via email or receiving more targeted guidance, were considered:

‘So I called some of the service providers straight through to supporting them, and closed the (accreditation system) down, and brought it into an internal provision where providers then can send documents through via email (...) The process is still there as a standard, but I can provide instant feedback and targeted support. Now the process is smoother and easier for providers.’ (Manager 6)

Managers, navigators, GPs, and service providers generally perceived a flexible approach to implementation, which allows changes to planned pathways or processes to respond to unforeseen challenges, as a key enabler to implementation.

Development of procedures and policies to support programme activities

Managers, navigators, and service providers expressed the view that the SP programme and the implementation process were not planned sufficiently from the outset. There was a notion among managers that the business case lacked detailed information and descriptions of work processes, which resulted in a weak basis for the programme’s implementation:

‘It was not thought through, planned out, there was obviously a business case of some description going somewhere that was signed off at a higher level but again it didn’t detailed all of the things that were coming in, because nobody has thought about the IH system for example, nobody has thought about who is going to own it’ (Manager 9)

‘There was never a clear plan, there were very good ideas, good visions, good kind of thought processes, but there was no crystal clear plan. That was lacking.’ (Manager 6)

Moreover, managers, navigators, and service providers reported that the absence of service user level agreements between partners resulted in the lack of shared knowledge and understanding of the different roles and expectations of organisations and individuals:

‘I don’t think there is that contract, service level agreement, or something like this. Which actually would be a very good idea to say, this is what is expected from you, this is what is expected of us, and this is how we work together. Because we are not sure what is expected from us and also, actually, about what we can expect from SP’ (Service provider 4)

The absence of service level agreements had adverse affects on stakeholders’ motivation, created conflicts and suspicion between partners, and delayed progress:

‘We can’t be the ones doing it all, that is not working. I think this belongs to the programme manager’s responsibilities, I am not sure what he is doing about this issue?’ (Manager 7)

‘That’s a reoccurring problem you see, we don’t know who is responsible to sign it off, so now we are just waiting’ (Manager 2)

Appreciation of roles and responsibilities

It is not only important that all parties understand the roles and responsibilities of individuals and agencies, but also that there is an appreciation of roles and responsibilities. Reported lack of appreciation of GPs’ roles and responsibilities at an operational level, such as referral processes and eligibility criteria, hindered the delivery of SP and resulted in inappropriate referrals:

‘referrals were coming in but they were not on the referral form, they were on scratch papers and random old envelopes’ (Manager 5)

‘there was no [*patient*] consent because it had not been signed by the GP on the official referral form (...) The processes were not being followed. (...) it essentially stopped delivery. It just didn’t happen.’ (Manager 5)

‘patients specifically coming to me for housing, for social care, for very complex issues that really are in the rounds of a social worker, or a nurse, or a medical professional, rather than [*for a navigator*] (...) just too complex for SP really’ (Navigator 1)

However, navigators acknowledged that it could sometimes be difficult for GPs to identify suitable patients, as the complexity of cases often became apparent only after the first session with the navigator. Although navigators believed that some patients’ needs were too complex for SP, they decided to work with the patients, as they had no options for onward referrals other than sending patients back to their GPs. It appeared that navigators worried about the patients with complex needs and were unsure about the availability of support options beyond SP:

‘There is the element of knowing that actually, yes that patient will take a lot of time and it is not necessarily appropriate for me to be dealing with them, but if I don’t then what happens to that patient? And it is very difficult if that sits with you and to know that.’ (Navigator 1)

Evaluation of the Luton SP programme

One of the major identified barriers to implementation was the lack of a clear evaluation framework. Managers and navigators reported that service delivery had begun before the intended outcomes, at a measurable level, of the SP programme and evaluation methods were decided:

‘we only developed that (*the evaluation framework*) while we have gone along. We gone in blind, thinking what are we going to get out of it? What do we want to measure out of it? You know you got your high level staff, but nobody have thought about the detail and it all just run with the high levels’ (Manager 9)

During the interviews, managers, navigators, GPs, and service providers named a range of intended outcomes of the Luton SP programme, including:

- Reduction in A&E, acute care, and unplanned admissions
- Cost savings for the NHS
- Reduction of diseases
- Improvement of patient health overall
- Patient empowerment
- Patient engagement

- Increased physical activity
- Improved mental wellbeing
- Mobilisation of communities around health

Although the named outcomes may all be relevant for SP in general, it seemed that there was no shared understanding about specific intended outcomes of the programme among stakeholders. This finding is underlined by a manager's perception that there was confusion about intended outcomes among stakeholders during the implementation process:

‘And if we could clearly articulate what we wanted to achieve (...) in terms of the outcomes, because there were confusions about: Is it physical activity? Is it self-efficacy? Is it mental wellbeing? You know, what is it we want to do?’ (Manager 1)

There was a notion among navigators and managers that the on-going discussions about the programme's outcomes and the evaluation framework were time consuming and hindered progress. Furthermore, to implement the on-going changes were frustrating and distracted navigators from performing their roles:

‘All these changes absolutely impacted on the implementation. I think it has got many things very confusing. I think it destructed the navigators from being able to focus on what they needed to focus on.’ (Manager 1)

‘I think that [*development of evaluation framework*] hindered us moving forward, because we had so many discussions about what we could and could not do (...) It was confusing for the navigators because they did not know which data to collect. So that was frustrating.’ (Manager 3)

It is interesting that managers believed that there was not enough time to plan the programme sufficiently because there was a ‘pressure from the system’ (Manager 9) to deliver the service:

‘The pressure from the system has forced something to happen that was not happy to roll just yet, because none of the real looking into it, behind the scene of what you are trying to do has been sorted out completely. I think it is just the planning of it, needed to taking longer before it was pressurised into it’ (Manager 9)

As the interview progressed, manager 9 expressed the view that due to financial pressures the focus changed towards demonstrating reduced use of resources and cost savings of the programme after a short pilot period, rather than meeting the patient related objectives. Hence, financial pressure were perceived as being responsible for starting the implementation before all required aspects were ready to be implemented:

‘So, I think it is just the planning of it, needed to taking longer before it was pressurised into it. But as I said, for me I think it was a financial pressure, because the system said we need to get that off and running because we need to prove that there is a cost saving by the end of the year.’ (Manager 9)

Communication and relationships

Managers, GPs, and providers generally expressed the view that on-going, clear, and effective communication between senior level executives across partner organisations, programme managers, steering group members, and providers is an important element of partnership working, and one of the most important enablers, or when absent barriers, to implementation:

‘that has caused delays to kind of patient pathways and processes being developed, because issues were not discussed and also because things were being done at manager level and then communication was not happening to update people on what was happening.’ (Manager 1)

In addition, participants attributed success to both good pre-existing relationships and newly built relationships over the course of the pilot between individuals and organisations. Good relationships were attributed to continuous, planned, and clear communication and vice versa. On the other hand, poor relationships and communication between individuals and organisations slowed down progress and hindered implementation:

‘The relationship between the other navigator and the GP was distorted, so their communication was really really bad...there wasn’t any I would say at all. SP never really started in this surgery with (Name of the navigator)’ (Navigator 2)

‘you need to trust the person and you need to be able to communicate with them. If you cannot communicate you can’t really build up a trusty relationship.’ (GP 3)

There was a notion among stakeholders that the navigators are the centres of communication, as they communicated with primary care staff, managers, and providers:

‘Navigators are the middle-men, they are communicating with everyone’ (Manager 2)

The importance of clear and continuous communication between the navigators and two specific stakeholder groups, namely primary care staff and service providers in the third sector, was frequently emphasised. The SP programme in Luton, essentially, requires a GP to recognise that a patient has a problem that could be addressed by non-medical sources of support. Thus, the starting point of the SP pathway is a GP’s referral. Given that GPs and navigators are involved at the start of the pathway, effective communication between GPs and navigators was perceived as crucial for the delivery of the programme. When the communication between navigators and GPs was discussed in the interviews, it appeared that the use of a shared IT system, called SystemOne (a centrally hosted computer system predominantly used in primary care in the UK), facilitated the communication between partners working in surgeries. Providing the navigators access to the existing clinical software facilitated on-going communication and allowed a continuous and shared delivery process:

‘So the SystemOne notes are very key, because on SystemOne I may record that I tried to contact this patient on these dates, I texted, I sent a letter, no response, none compliant, close. The GP will pick that up and say, oh why didn’t you uptake SP? What was the reason for that? The GP can then explore that and process a re-referral and that has been quite successful (...) And we do that quite a bit and that has worked.’ (Navigator 2)

Although all navigators and GPs had access to SystemOne, it was not an agreed path of communication in all surgeries. The next quote illustrates that not all GPs had agreed communication pathways with navigators:

‘Ahm, I don’t know [*about SystemOne notes from the navigator*]. There is no sort of direct phone number or anything, I suppose we could task her, that might be a possibility?’ (GP 1)

As demonstrated by the next quote, the absence of agreed communication pathways between partners resulted in poor communication:

‘Well, I do the referral form and then leave it at reception, and then apparently the navigator comes and picks it up. And that is the only communication we have (...) there is no sort of feedback about the referrals we have done’ (GP 1)

GP 1 has attributed the low number of referrals he is making to SP to the poor communication with the navigator. Poor relationships and communication often goes hand in hand with providers' disengagement and de-motivation, resulting in barriers to implementation:

'if the navigator is saying, look I am here, I am seeing patients, are there any queries you would like to discuss let me know, they would get me to refer more patients, and that is all it takes (...) give us positive feedback and talk to us, so we will do more and more.' (GP 1)

Co-location (when navigators are based in surgeries) was identified as an important factor promoting integration, on-going communication, and relationship building, which were perceived as necessary elements for the formation of new integrated teams:

'Being in the surgery is key (...) Because I think a lot of it is around the networking, seeing the navigator, just grab someone in the corridor and say, oh I have seen X and X today, and that kind of staff (...) You know, just having that quick chat with the doctor as they come out of their consultation room for five minutes.' (Manager 1)

In line with this manager's view, navigators reported that working in the same building as the primary care team facilitated the creation of new integrated teams and improved the quality and frequency of communication:

'It is a lot easier to communicate. I speak to the doctors regularly, I speak to the practice manager regularly, we communicate very well.' (Navigator 1)

Managers and navigators agreed that in order to implement SP in general practice, it is essential to communicate and build relationships with the wider primary care team, not only with the GPs:

'It is the practice manager that kind of unofficially runs that place [*the general practice*] really, so it is key that the practice manager is involved and that there is constant communication because not only do they know how all the things work within the GP practice, they are the ones who can disseminate information and set up the pathways and systems for SP within the practice.' (Manager 3)

'With the surgery team the communication is key, with everyone within there, because it might be the GP who is referring, but the practice manager, nurses, administrators, and receptionists who need to be aware of the programme [*SP*] and how it works because they are

going to either fill questions about it from patients, or the navigators are going to ask them questions about where things are and what happened, room availability, etc.’ (Manager 5)

Like service providers, all interviewed navigators expressed the view that communication between service providers and navigators is also essential to provide continuous care and to improve service user experience. One service provider highlighted that clear and continuous communication with the navigator allowed the fast resolution of practical issues that hindered service delivery:

‘it has happened at various occasions, where the navigators are coming back to us to say, this person is going to use the card and it does not work (...) So the navigators would communicate, they would send me the number of the membership card that needs activating, and then I can just type in this membership number and press enter. Then they [*service users*] can use the service again.’ (Service provider 6)

On the other hand, the absence of good communication between navigators and service providers were highlighted as a major barrier to service delivery and programme implementation:

‘we had a problem with a provider recently (...) my referrals did not go anywhere, they were not answering the phone, they were not answering emails, it delayed sending patients there, and ultimately that outcome happening for that patient.’ (Navigator 1)

Participants attributed the poor communication partly to being thrown into the pilot without gaining enough information beforehand and having enough time to develop new relationships with partners and communication pathways, required to build new integrative teams:

‘it [*the communication between partners*] could have worked better and the whole introduction processes sort out more, more time put into developing those relationships, between the partners, the navigators, the providers, before just throwing everybody into a ring and say: right now we are providing SP.’ (Manager 9)

Shared knowledge and understanding

Lack of shared knowledge and understanding among all stakeholders of the scope and aims of the Luton SP programme, as well as the roles and responsibilities of individuals were identified as major barriers to implementation. Managers have reported that uncertainty about

the contributions and responsibilities of individuals and organisations have resulted in tension between partners and delayed the completion of work processes:

‘I think the clarity of the roles could be improved in terms of making sure that everybody knows what is their role. I think understanding expectations and also understanding the expectations of each other’s roles...that is missing.’ (Manager 2)

‘the work was passed on to us, we were like hold on, hold on, hold on, we are not actually doing it (...) because our expectation as (name of organisation) was to facilitate and set up, but (name of partner organisation) obviously thought we are going to lead and do staff, because we received all these emails can you do, can you do, can you do...No!’ (Manager 9)

Managers and navigators partly attributed the lack of role clarity, shared knowledge, and understanding of the pilot among stakeholders to the fragmented and unclear communication pathways:

‘it sits with one person who is coming to the SP meetings from the staff and that is it. They do not have actually gone back and discussed it in a big open meeting at the practice and really explained what it [SP] means so that everyone understands and knows what it is’ (Manager 9)

This finding highlights that communication, relationships, and a shared understanding among individuals and organisations are inextricably linked.

In addition, the findings presented under the theme ‘*Development of procedures and policies to support programme activities*,’ indicate that the absence of service level agreements contributed to the lack of shared understanding among partners in the Luton SP programme, too.

Not understanding the goals, opportunities, and scope of the SP programme from the outset has resulted in frustration of service providers in the third sector:

‘a lot of providers thought this will be a money making scheme so that they sign up to this programme and you get more customers basically and that was almost their carrot to get into it but in reality it is not like that (...) Providers then question SP, they say what was the point for me then to sign up for it. I have done all this work to get accredited, it has taken weeks, months, hours depending on where they are at. And then there is not yet anything to see from it.’ (Manager 5)

Interviewed service providers and managers expressed concerns about the sustainability of the Luton SP programme, given the increasing frustration and dissatisfaction with the number of referrals from SP to third sector organisations during the pilot period.

Human resources

Navigator's role

Managers and GPs reported that the navigators' skills and experiences were critical for successful implementation and outcomes of SP. Most of the navigators were working in social and health care environments before and had vast experience in working with healthcare professionals, vulnerable people, mental health patients, and motivational interviewing. The next quote demonstrates that a manager attributed a navigator's skills and experiences to the implementation progress and positive outcomes of the programme:

‘So, somebody who is real proactive, experienced practitioner, understanding the in-depth nature of some of these clients for example safe guarding, domestic or housing situations, benefits, low level mental health, crisis, all of those kind of things, I think that our navigator has experience of. And also it is an experienced practitioner in terms of motivational interviewing and working with clients, so all of that is invaluable. If I think that we would have somebody (...) with pretty much none of that experience (...) I think we would not have had developed the project at the rate we did and also I don't know if the outcomes would be as successful. So the navigator with all those skills was really crucial for the implementation of SP.’ (Manager 1)

Managers and GPs emphasised that every surgery is unique in its culture and ways of working. The skill of navigators to work in a flexible way and adjust to the existing work routines and flows of each surgery was identified as an enabler to implementation:

‘Particularly when you are working with general practice, there are very different ways of working from one practice to the next, you got to be quite flexible and effectively you got to be able to fit in with their culture and way of working going forward. (Name of navigator) has been really good in that.’ (Manager 8)

Stakeholder engagement

Managers reported that it was difficult to secure primary care staff's engagement in the pilot, as there was a notion of skepticism towards SP and taking on new roles among health care professionals:

‘There is some skepticism around it [*SP*] ‘Our job is just medical’, or ‘this social staff is not proven’, or ‘I don’t believe it can work’. ‘Why can’t I just tell them to do it themselves?’ So that is a barrier, to involve GPs and to get them to accept that it is part of their job.’ (Manager 4)

Managers believed that part of the expressed skepticism is due to the lack of robust scientific evidence on the effectiveness and outcomes of SP:

‘GPs need to see evidence based outcomes. And actually there is not anything yet, so far (...) Yes, numbers exactly. And the fact that it is going to really benefit them and their patients obviously to do this, if they know that they are going to save x amounts of GP slots, and x amount of pounds, and not sending people in to A&E because they have went through the SP programme - then they would probably say, we definitely do this.’ (Manager 1)

Managers also emphasised that the rather weak evidence base on SP at the time the Luton pilot was implemented, together with the financial pressure in primary care, convoluted the initial engagement of GPs:

‘It is very hard to get somebody to buy in to something that you cannot prove it is going to be a benefit when they are already stretched.’ (Manager 9)

In line with the managers’ assumptions, all interviewed GPs questioned the effectiveness of SP and felt that it is important to have robust scientific evidence on the outcomes of interventions implemented in primary care:

‘a lot of doctors like the evidence, and sadly there is not much (...) I suppose our training, general practice, is very much evidence based and everything is evidenced based.’ (GP 3)

‘The second challenge is that what is the outcome of SP, like for example, when are the results available? Is there a real difference or did patients just had a good time? I don’t know the answer and I am missing the evidence. I hope we will get some numbers soon, I am waiting.’ (GP 2)

In addition to the challenge of the initial disengagement, managers and navigators emphasised that where key groups, for example health care professionals, were not engaged throughout the implementation phase (i.e. no on-going engagement), it was difficult to make progress:

‘I think the reason why we are not further into this project, and partly the reason why we have not being able to scale up quite so quickly, is that for some of the pilot practices engagement has been difficult.’ (Manager 8)

Managers and navigators believed that low engagement of GPs is mainly reflected in their low numbers of referrals to the programme and failure to follow referral processes. As the SP pathway requires a referral from a GP, low engagement was perceived as a strong barrier to take SP forward. Managers and navigators attributed low referrals to the nature of SP and that it is based on the biopsychosocial model of care. Working beyond the traditional biomedical model focusing on clinical diagnosis, was perceived as a major factor influencing referral rates:

‘If you think about the way in which the NHS traditionally works within England, it is very much a medical model. People get sick, they come, we treat them. So now saying, actually what we want to do is prevent illness, promote wellness - this is down stream work. So we are moving outside of the traditional medical model, now embracing a much more social model, psychosocial movement, kind of concept. So leading some of the clinicians down that route was a challenge.’ (Manager 7)

GPs attributed low referrals to the novelty of SP, the difficulty to remember it as an additional option in primary care, and to make it a part of their routine practice:

‘I suppose the main hindrance [*for referrals*] is that it is hard for us to make it a routine to refer patients. We should be doing it routinely but we don’t (...) I think it is just because we have never been used to it and because it is new. You know it is really new, and sometimes you forget that there are more things we can offer.’ (GP 1)

All GPs and navigators expressed the view that continuous engagement in the pilot requires both a cultural change at an organisational level and a behavior change at the individual level:

‘I think sometimes the GPs have a cultural change that they need to go through, to get them through that kind of barrier [*of not referring*]. It is part of a change in the whole primary care culture I suppose’ (Navigator 2)

‘it [*SP*] was initially slow to take of because this is a new concept for general practice, I think, the world of NHS is pretty much physical health driven, it always has been. SP requires a change in thinking and a behavior change in a way.’ (GP 3)

Staff turnover

Since the SP programme employed a relatively small number of staff working on the pilot, it was vulnerable to staff turnover and the attendant delays caused by recruiting and training new staff. Managers and navigators generally expressed the view that a high staff turnover resulted in on-going changes within the implementation team, which had adverse effects on the implementation process and the sustainability of the programme:

‘So all the way through the programme it has been a bit like somebody started, then somebody else comes in, and then they leave, and somebody else comes in (...) So there hasn’t really been a consistency’ (Manager 5)

Managers expressed the view that the absence of a smooth transition period between previous and new employees, including a handover phase, was partly responsible for the fragmented and delayed implementation of the programme:

‘The problem here is that one person leaves, and then there is a gap, hindering implementation. Then after a while a new person comes in and needs to start from scratch, as the person who used to work in the role is gone and cannot do a handover anymore. And shadowing isn’t possible either. How can someone expect a continuous process then? Of course it is fragmented.’ (Manager 3)

‘But the thing is that there was no real handover from (Name of manager) (...) If you have a messy handover you are always picking up pieces.’ (Manager 6)

Managers reported that one of the biggest challenges was the departure of staff with specific tasks and individuals heavily involved in management. For example, the sudden resignation of a navigator and the delays in recruiting a new one, created a key barrier to implementation:

‘So we ended up with one navigator for a while that hindered the implementation (...) you cannot deliver without a navigator, the navigator is a key person, the navigator is key. No navigator, no SP.’ (Manager 2)

In addition, a manager identified the resignation of a key individual responsible for developing the job description, support structure, and training programme for navigators, and the lack of her replacement, as a major barrier to implementation:

‘when she left that was a great issue, a great barrier to implementation, and it happened very sudden (...) the fact that she left, we just had a missive gap in the place in terms of the organisational memory, in terms of the expertise around mental health and workforce development training (...) When key staff leaves and there is a lack of replacement of key staff and key skills...that is a huge barrier!’ (Manager 4)

As the interview progressed, manager 4 expressed the view that sharing tasks among managers to fill the gap after a staff member with specific tasks left resulted in long-term adverse effects on delivery and implementation. As demonstrated in the following quote, manager 4 attributed the support issues experienced by the navigators to the lack of replacement of the member who was responsible for the development of the support structure and role of navigators:

‘She was the one who would actually did the main work on drafting the navigators’ job description, so she would have been the lead, the go to person for navigators around the sort of developmental needs, and she would have raised that in the steering group. I am sure a lot of that got lost as well, in terms of supporting them [*the navigators*] and going forward’ (Manager 4)

For some managers, the departure of a lead manager signalled the end of the pilot’s success, since they believed that the leadership style and passion of the lead manager was key to keep the team motivated and successfully implement SP in Luton.

Organisational readiness

Information technological infrastructure

The original ambition was to develop a shared IT system between all front-line providers across the Luton SP pathway to allow for efficient service user management throughout the pathway and to facilitate data collection, communication, and information sharing. An external company was in charge of developing the shared IT system, in collaboration and with support from the steering group. Delays (up to 18 months at the point of the interviews) in developing the IT system were identified as a strong barrier to implementation:

‘IT has been a massive barrier for us, I am sure you will hear that from all others’ (Manager 4)

‘As I said, we didn’t actually go live, we put off going live for good six to eight months to when we should have gone live, because we were supposed to go live but we postponed and

said we wait for the IT system, and it did not come. It was like we can't keep waiting, we need to do something because these guys [*the navigators*] are in post.' (Manager 9)

Managers attributed the delays in the development of the IT system to different factors. Firstly, factors related to the external company, such as high staff-turnover resulting in a fragmented development process, communication issues within the company and with the steering group, and the failure to keep to agreed deadlines and work processes were frequently mentioned. In addition to these external issues, managers blamed restricted financial resources and the shared approach to management that lead to a lack of ownership and responsibility for the development of the IT system, for the slow progress. Lastly, managers reported that they have underestimated the required time to resolve issues around data collection, information governance, and patient confidentiality, as well as the legal and technical limits to information sharing.

To implement the SP programme besides the absence of the shared IT system, a paper version of the programme was developed. The progress of the implementation was significantly slowed down while this alternative arrangement was made. In the paper version, referrals between providers and initial data collection were done on paper. Collected data were then entered into a Microsoft Excel sheet for analysis. As the following quotes indicate, delivering the pilot without the planned IT system increased the workload for involved stakeholders:

'it is not ideal having the paper version at all, because there is so much extra admin that has to be done, on all parties not only the GPs and the navigators, but all of them has got this extra amount of paper work' (Manager 9)

'manual data entry and duplicating data entry, receiving and processing referral forms on paper, that had taken up a massive chunk of our time that we should be face-to-face with patients.' (Navigator 2)

Managers emphasised that switching to the paper version has also hindered the planned evaluation of the pilot, as pre- and post-intervention data of interest and the socio-demographic characteristics of service users were not collected in a standardised and comparable way. Moreover, service user engagement with the referred activities and dropout rates were not monitored in a digital way as originally planned.

To enable data sharing and communication across health and navigator teams, navigators were allowed to have access to SystemOne. In order to access SystemOne, a NHS smartcard

is required. A navigator reported to be employed for a couple of weeks before she was informed about the need of a NHS smartcard:

‘So I haven’t got a card, and there was no mention at first about the process in terms of how to get it, you know. It felt like weeks and weeks down the line, I think eight (...) but the managers have not said anything about it [*NHS smartcard*].’ (Navigator 4)

As navigators were employed by community organisations, it was a time consuming, complicated, and bureaucratic process to get a NHS smartcard:

‘I have experienced difficulties in terms of getting my RAO1 signed off (...) It needed being to be signed of by the practice manager first, and (...) there were concerns about who was going to take ultimate responsibility for me having a smartcard. And that she wanted confirmation and input from the CCG, so all of that has been going on the last weeks (...) The CCG said that they can’t actually sign the form on my behalf, it needs to be the surgery.’ (Navigator 4)

As the navigator required a smartcard to deliver the service, the implementation of SP in two surgeries was hindered while the navigator was waiting for the card required to access SystemOne and the computers in the surgery:

‘everything is hindered by me getting a smartcard.’ (Navigator 4)

In addition, navigators experienced problems with using their work laptops, programmes to sign service users up for referred activities, and to connect to the Wifi network of surgeries:

‘I had various technical problems, which had impacted on me and my ability to do work. For example, internet connection on the laptop, problems with the membership programme where I sign people up onto. (Name of an organisation) memberships did not work for weeks when I got my new laptop, which massively delayed me getting these referrals through.’ (Navigator 1)

‘In order to get Wifi access in the surgery, you have to get another form completed, so that they then can add you on the Wifi. But this particular surgery don’t allow anybody Wifi access.’ (Navigator 4)

In general, the absence of a supportive IT infrastructure, required for the implementation and delivery of a programme across the social and health sector, was perceived as a strong barrier to implementation.

Navigator-ready surgeries

Managers reported that the preparation of surgeries to deliver SP took much longer than initially anticipated and therefore turned into a major barrier to implementation:

‘This just goes to show how key it is getting all the dots in the row. So to make sure the GPs and everything else is in place before the navigator gets in and is ready to go. Because we employed the navigators and then the surgery wasn’t ready, so yeah...we couldn’t go forward.’ (Manager 5)

A manager attributed the delays in getting surgeries ready to host navigators and deliver the programme to the pre-existing capacities and resources in place. Instead of focusing on the capacity of surgeries and available resources to implement the pilot, decisions on selecting the first pilot practices were based on enthusiasm and interest of the practice team:

‘When we were looking at the criteria for which practices we should go forward first, I guess we heavily weighted that criteria on enthusiasm and will from the practice perspective. But actually we didn’t see the challenges they are going to have in terms of room availability, the clinicians to support this (...) and whether or not they are able to invest the time with this going forward to getting this work. That became a bit of a blockage’ (Manager 9)

In addition, managers reported that the engagement of primary care teams and the communication and negotiations with practices were more time consuming and challenging than initially anticipated. Due to pre-existing and contextual circumstances, such as resource and infrastructure issues to deliver primary care, the implementation of SP was often not perceived as a priority:

‘So for a couple of our project pilot practices, they got their own resource and infrastructure issues to deliver core primary care services, which absolutely have to come first, and this [SP] for them is seen as a bold on, as an addition (...) they are commissioned to deliver core primary care and they absolutely need to make sure that happens first, and then SP, unfortunately at this point, would come second.’ (Manager 8)

The surgeries not being ‘navigator-ready’ resulted in a waiting time for navigators to move into surgeries to perform their role:

‘I was meant to start in (name of practice), but they had not completed the meetings in this practice. So they have spoken to the practice manager but they have not spoken to the doctors, so when I got in, a couple of weeks after that they started to speak to the GPs.’ (Navigator 3)

Uncertainty about when navigators can start working in their roles and the absence of clear and consistent communication from central pilot leadership about action plans and timelines had adverse affects on navigators’ motivation and engagement:

‘I had a month of being at my bosses office, doing whatever else I could do in the meantime to prepare myself but with no actual referrals, no patient contact, not being in clinic (...) And no one was communicating with us really, it was very frustrating you know, what was I supposed to do with my time?’ (Navigator 1)

‘We are [*navigators*] employed for weeks and weeks, months, and haven’t seen a single patient yet. It is difficult to you know, keep motivated and positive sometimes, because we don’t know, I have no idea when I will actually be in the surgeries seeing patients.’ (Navigator 4)

Managers and navigators highlighted that the lack of available rooms for navigators in the participating surgeries remained an issue throughout the implementation process. Again, this issue was linked back to the pre-existing circumstances in surgeries, i.e. the physical available space to host a navigator. A navigator who has a desk in an open office space, instead of a designated room due to limited room availability, highlighted that the surgery’s room availability determined the days and times of appointments with service users. The following quote demonstrates that this has delayed meetings with service users:

‘What makes it difficult is not being able to get patients into clinic as quickly as I would like to. That is not just the patient, that is also the availability of rooms in the GP surgery.’ (Navigator 1)

Another navigator emphasised that not having a designated room resulted in a fragmented delivery process and increased the navigators’ workload. When meeting a service user in any available room in the surgery, the navigators don’t have access to the computer, their files, and documents stored at their desk during an appointment. Consequently, the navigators can’t

conduct research for the service user, or go through relevant files and documents, during their appointments. Therefore, after accessing the relevant information, navigators need to contact the service user, usually via phone, to follow up on a meeting:

‘In your room you have your information ready. So now if I am seeing someone here [*in a clinical room*], I might then have to log on to a computer, which is difficult, to find out some information or I may need to get back to them (...) I cannot leave them, run upstairs, come back, run upstairs.’ (Navigator 3)

Accredited service providers in the third sector

Managers and navigators emphasised that the range of accredited service providers was very limited when referrals to the programme started. Although a limited provider base to start with was generally perceived as normal, it restricted navigators to refer patients to available services, rather than following a more patient centered approach:

‘That [*the number of service providers*] has been limited, right at the beginning, that was really limited. So having more, a range of providers, would have made a difference and possibly people would have got a more bespoke programme or intervention because actually they [*navigators*] were fitting people into things because that was all that they had’ (Manager 1)

Managers and navigators reported that the service provider base has not increased sufficiently to meet the needs of referred patients in a timely manner during the pilot period:

‘We haven’t got enough service providers, we haven’t got enough choice. That should be growing much faster than it is but it is not.’ (Navigator 2)

Managers attributed the slow progress of increasing the range of services on offer to the lack of a programme manager and to the complex and time consuming accreditation process (as discussed earlier in this section), as it hindered service providers to come on board:

‘The providers were limited, because there were issues with setting them up and to get them accredited.’ (Manager 5)

The accreditation process, for interviewed service providers, took between two and eight months. When a provider with a specific service was in the accreditation process, navigators

asked service users to wait till providers were accredited to access their specific services. Ultimately, this has hindered the delivery of the programme:

‘navigators were also waiting for services to become accredited and they were telling patients to wait for accreditation, so it then hindered delivery’ (Manager 5)

Furthermore, navigators emphasised that some of the few available service providers had long waiting lists. This also delayed the access to services, as well as the delivery of SP:

‘they have a twelve week long waiting list, also when going through SP. That is a long time for someone to wait who is in crisis, or who is in pain, who suffered trauma, and who had shared his problems for the first time.’ (Navigator 2)

‘Some referrals are not processed for weeks and weeks and weeks because there is a long waiting list (...) So sometimes this patient, I can’t do anything until the service has come through, so that is a big barrier.’ (Navigator 1)

Navigators and managers expressed the view that it is particularly challenging to establish a strong service provider base for service users with diverse and complex needs and medical histories. Having wide eligibility criteria including patients with (i) COPD, (ii) mental health issues, (iii) diabetes, (iv) carers, and (v) ‘other issues’ from the outset, was perceived as a barrier to develop a strong provider base to successfully deliver and implement the programme:

‘I just think that we got a lot, we chosen a lot, and I think if we would have chosen only one, low level mental health for example, we could really fine tune those services and really made a much better impact. We haven’t got enough of the right services to fill the gaps.’ (Navigator 2)

‘You can say on diabetes, we need providers who are going to these three or four things, we know it will be around physical activity, social engagement, we know it is about diet. Those are the things that will impact on people with diabetes and who are pre-diabetic. These would be the numbers, they would be relatively small, but in terms of getting the infrastructure in place, that would be the right approach’ (Manager 7)

Manager 7 attributed the selection of wide eligibility criteria to the underlying aim to increase the attractiveness and potential benefit of the programme. However, while the attractiveness

of the programme may be lower with narrower eligibility criteria, manager 7 believed that it would be more realistic to build the required service provider base:

‘By going for such a wide range of conditions, mental health, diabetes, these are big tickets. I understand that it drives the numbers up, it addresses the big issues that are coming through the primary care population, and I think if you would have one condition, or two to the maximum, the numbers would have been smaller. Therefore the potential return would be smaller, and therefore the programme would not be so attractive, but it would have been more realistic.’ (Manager 7)

Contextual factors

Local infrastructure

When the SP programme was planned, Luton had already a well-developed third sector, consisting of potential service providers for the programme. As the following quote illustrates, the existing infrastructure in Luton was identified as a supportive contextual factor to foster implementation:

‘Luton had quite a good infrastructure (...) So that infrastructure was there for us to plug into, it was in place, we did not need to build that infrastructure’ (Manager 7)

A manager highlighted that the pre-existing relationships with the third sector and credibility of the team leader were key enablers to working with- and benefitting of- the available infrastructure in Luton:

‘I think Luton had quite a good infrastructure, so the team was actually able to talk to the community and there was a degree of confidence, you know that comes from the work (name of team leader) and his team have done. I don’t know for how many years, so they actually had some credibility (...) So they knew people they could talk to, they were able to facilitate, they had relationships’ (Manager 6)

National policy context

Participants described how the policy priorities facilitated the implementation of SP, for example, that the NHS is investing in integrated care through the Better Care Fund. Furthermore, the alignment of SP with national policies, such as the NHS Five Year Forward View or GP Forward View, were identified as being actively helpful in demonstrating the relevance of SP to decision-makers:

‘It [*the policy agenda*] does absolutely help. If you think about the Five Year Forward View, the GP Forward View (...) at the highest level, SP is there. And I think that has helped, it has been an enabler in terms of more locally where you have senior people and managers, who do not necessarily understand or buy in to the concept of SP. It is very helpful to be able to say: but actually looking at the policy it is there.’ (Manager 8)

Managers and GPs expressed an awareness of the on-going changes away from the traditional biomedical model of the NHS, which are driven by the previously named policies. They highlighted that the NHS is moving towards a more biopsychosocial model of care, which in addition to biological factors takes the wider determinants of health into account. This shift within the NHS is believed to create a supportive climate for the implementation of SP programmes:

‘historically it is the biological factors that they [*health professional*] historically have been trained to look at and to identify, but more and more they are understanding that it is the biological, it is the psycho, it is the social, it is all of that together and we need to be thinking about a more holistic view for the patient (...) Through the multidisciplinary teams that we have got in the GP practices to some degree now, there is an ability to quite quickly link in with social care to start picking up on adverse social factors that then have a health impact.’ (Manager 8)

Closure of pilot practices

The Luton SP programme was implemented in the NHS, a context that is characterised by constant structural change and policy reform. Due to national changes in the NHS, a surgery was closed down 18 months after the start of the pilot. The closure of this surgery resulted in unforeseen barriers to the implementation of SP. Firstly, after the closure of the surgery was confirmed, health professionals stopped referring patients to the programme:

‘(Name of surgery) were not referring anybody and that is probably because their patients are slowly moving off and they are not going to refer them if they are not going to complete. So they probably thinking: ‘Well we are closing in eight weeks, what is the point?’ And not knowing where people are going.’ (Manager 9)

Secondly, the closure of one pilot practice increased the workload of another pilot practice in the area, as many new patients had to be registered. The increase in workload related to administrative and practical tasks, resulted in the negligence of the implementation of SP, significantly delaying progress:

‘And (Name of surgery) are probably so stretched at the moment by registering the patients that are coming across and doing their initial assessment appointments that they are not thinking about SP. So that is their focus at the moment, to get these new people registered make sure their initial registration appointments are done, tick boxes that they are all on the right registers for whatever diseases they have got, and to make sure their care management is right.’ (Manager 9)

Given that the structural changes in the NHS and the policy context impacted on the implementation and scaling-up of the programme, managers, GPs, and navigators identified contextual factors as key, but also sometimes uncontrollable, barriers and facilitators.

8.2.3 Summary of findings

Findings showed that the operational processes, communication and relationships between individuals and multiple organisations, the development of the evaluation framework, shared understanding among stakeholders, human resources, and organisational and contextual factors affected the implementation of the Luton SP programme. Implementing SP requires partnership working across the social and health sector, which is facilitated by preparatory activities involving all potential stakeholder groups and clear and constant communication within and across teams and organisations. Clear and constant communication was also perceived as a basis for maintenance and development of good relationships as well as shared understanding of roles, visions, and aims among stakeholders and partners. The absence of careful and realistic planning of the (i) programme, (ii) the implementation process, and (iii) objective led evaluation, were identified as key barriers to implementation. Adapting the programme throughout the implementation process allowed the timely response to unforeseen barriers and challenges. High-staff turn over hindered the implementation and sustainability of the programme. Characteristics and skills of navigators were believed to impact on the progress of the implementation and delivery. Therefore the recruitment of individuals with experience of working in health and social care environments with vulnerable people was believed to be beneficial. Given that the SP pathway in Luton starts with a referral from a GP and is based in surgeries, disengagement of primary care staff was perceived as a strong barrier to implementation. Problems with the development of a shared IT system accessible for front-line providers across the pathway significantly slowed down the implementation while alternative arrangements (a paper version of the programme and providing SystemOne access to navigators) were made. Negotiations and preparations of surgeries took longer than anticipated, which was attributed to the pre-existing circumstances, such as limited resources and capacities to implement the programme. A limited service provider base was identified as a barrier to the patient-centred delivery of the programme. A wide eligibility criteria, as well

as the complex and time consuming accreditation process and lack of a programme manager were believed to be responsible for delays in building a strong provider base. Finally, participants discussed a number of practical barriers and facilitators, which were related to the organisational and policy context in which SP was implemented. The existing local infrastructure in Luton and the supportive national policy context were identified as factors facilitating the implementation of SP. Structural changes within the NHS were identified as barriers to implementation and up-scaling of SP.

8.3 Objective 3: Patient uptake and service user adherence to the Luton social prescribing programme

8.3.1 Participants

Ten service users were interviewed. Table 13 and Table 14 outline the characteristics of interviewed service users, the reasons for referral, type and number of referred services, and their status at the point of the interview. Nine of the interviewed service users were female and one male. Four were unemployed, two retired, two in full-time employment, one was a carer, and one a student. Most were married, two single, and one was legally separated. Six of those interviewed were White British, one was Black British, one Pakistani, one Asian Pakistani, and one Egyptian. The age range of participants was 27 to 66 years. Reasons for referral, type and numbers of referred activities, and the level of engagement, varied between interviewees (Table 14).

Table 13: Service user characteristics

Service user (SU) ID	Gender	Employment status	Marital status	Ethnicity	Age
SU 1	Female	Unemployed	Married	White British	56
SU 2	Female	Unemployed	Legally separated	White British	59
SU 3	Female	Retired	Married	White British	66
SU 4	Female	Retired	Married	White British	64
SU 5	Female	Unemployed	Married	Egyptian	47
SU 6	Female	In full-time employment	Married	White British	39
SU 7	Female	Carer for mother and husband	Married	Asian Pakistani	29
SU 8	Female	Unemployed	Single	Pakistani	34
SU 9	Female	Student	Single	Black British	27
SU 10	Male	In full-time employment	Married	White British	54

Table 14: Reasons for referral, type and number of referred services, and status at the point of the interview for service users

Service user (SU) ID	Reasons for referral	Type and number of referred services	Status in the programme (at point of interview)
SU 1	Depression and anxiety, unemployed and needs help to find a new job, weight loss	Job centre support (1), physical activity (1), social activity (1), and sewing group (1)	In process: Engaged with job centre appointments, engaging with physical activity, waiting to hear back from sewing group, planning to engage with social activity (not started at point of interview)
SU 2	Depression, targeted physical activity to support recovery, loneliness	Mental wellbeing services (1), support group (1), and physical activity (1)	Finished: Engaged with mental health services did not engage with physical activity
SU 3	Depression, loneliness, sedentary lifestyle	Art class (1) and physical activity (1)	In process: Engaged with art class dropped out of physical activity
SU 4	Carer, poor stress management skills	Meditation (1), physical activity (1), massage therapy (1)	Finished: Dropped out of meditation, did not engage with physical activity, engaged with massage therapy
SU 5	Back pain, loneliness	Massage therapy (1)	Finished: Engaged with massage therapy
SU 6	Weight loss	Weight management (1)	Finished: Did not engage with service
SU 7	Weight loss, depression, stressed, carer	Physical activities (3) and mental health service (1)	In process: Engaged with physical activities, waiting to hear back from mental health service
Su 8	Stressed, mental health problems, back pain, functional barriers	Housing advice (1), social and family workers (1), legal advice (1), Community service (1)	In process: Engaged with advice and social services, did not engage with community services after first visit
SU 9	Mental health problems, weight loss, housing problems, loneliness, functional barriers, issues with her son	Physical activity (2), weight management (1), Housing advice (1), community service (1), Children centre (1)	In Process: Engaged with advice service, and one physical activity, waiting to hear back from weight management service, did not engage with one physical activity, community service, and children centre
SU 10	Weight loss, depression	Physical activities (2), mental health service (1)	In process: Engaged with physical activities and mental health service

The characteristics of interviewed GPs and navigators are outlined in Table 10 and Table 11 (section 8.2.1), respectively.

8.3.2 Findings

Themes relevant to the uptake and adherence to the SP programme were initially identified from the qualitative data. The findings are presented in two sections to illustrate the uptake of primary care patients (section 1) and adherence of service users to the SP programme (section 2), from the service user, navigator, and GP perspective.

Section 1: Uptake

This section provides the findings from the analysis of the service users' experiences and navigators' and GPs' views of factors affecting the participation of primary care patients in the SP programme and engagement with the initial appointment with navigators (uptake). Five themes were identified: Trust in General Practitioners, perceived need and benefits, programme design, patient expectations, and stigma of psychosocial problems.

Trust in General practitioners

In the Luton programme, primary care patients had to consent to be referred to the SP programme by their GPs. GPs have expressed the view that patients' trust in GPs is an important factor promoting the involvement of primary care patients in SP:

'I suppose it just helps if you know the patient a bit and that they trust you, so they think, oh well I will give it a go. If you are trusted it is easier than if you are a new clinician.' (GP 3)

The following quote shades light into the doctor-patient relationship from the perspective of GP 2. This quote indicates that patients trust their GP because of their position in society, power, and knowledge:

'People listen to us, they trust us. The area we work, people look at the doctors like differently (...). So for example, the doctor gives them anything, they will take it. If doctor advises them something they will take it very seriously. If doctor asks them to not take it, they will not take it.' (GP 2)

In line with the GPs' assumption, service users have highlighted that they have agreed to be referred to the SP programme because they trust their GPs' advice and judgments:

‘the thing is I know Dr (Name of GP). We know each other for so long, I trust him. And I trust him that he knows me well enough, so I said yeah okay.’ (Service user 3)

‘Since the surgery was open, I trust her [GP]. She is a very nice doctor she sits and listens to you. I took notice of what she said, I knew I could trust her.’ (Service user 2)

It is interesting that all navigators expressed the view that primary care patients’ trust in an intervention is a key factor affecting their decisions on uptake. Navigators believed that patients perceived them as part of the primary care team because they work with GPs and are based in surgeries. As indicated in the following quote, navigator 2 believed that the pass over of trust from the GPs to the SP programme and the navigators, promoted patient uptake:

‘So I think they are coming to an appointment because they trust the GP and you are part of the clinic, so they think they [navigators] are part of my surgery and they are part of my clinical team. And I do really believe that because I think if that would be in a community centre they would not turn up. So, the power of the GP, it is about associations and accreditation, you know you are associated with that surgery and that GP sort of told them about you, of course we all trust our GPs explicitly. And therefore they would trust their judgments and their recommendations.’ (Navigator 2)

In line with the navigator’s believe, a service user emphasised that she trusted the navigator because she trusted her GP who made the referral:

‘I suppose I trust her [the navigator] because Dr (Name of GP) referred me to her. So I trust him, so I trust her, because I trust him.’ (Service user 3)

Another service user reported that she agreed to go to the first appointment with the navigator because it was held in the surgery she used to go to:

‘He [the navigator] called and I was kind of like...first I didn’t actually believe it was him but then when he mentioned the surgery and to come to the surgery I thought maybe yeah, it is more legit.’ (Service user 9)

In contrast with the perception that trust in GPs promotes patients’ uptake of the SP programme, GP 2 emphasised that some primary care patients refused to be referred to SP because they are entrenched in the medical model and trust their GP exclusively:

‘some people may think the doctor is a drug (...) Some people, they don’t trust anyone else apart from seeing the doctor.’ (GP 2)

Perceived needs and benefits

The perceived need and benefit of SP was identified as an important factor promoting the uptake of the programme. Service users reported that they have recognised that they need help to deal with their non-clinical problems. As the following quotes indicate, feeling the need for help and realising the potential benefit of the SP programme drove primary care patients’ decision to get involved with the programme:

‘One question was: ‘Do I need help?’ And my answer was: ‘Definitely yes!’ And it all sort of started from there really.’ (Service user 2)

‘I was struggling to do simple things like putting my socks on, wiping my bum properly. Physically working...I was getting out of breath because I was carrying extra weight (...) I am hoping, I am hoping it [*social prescription*] gets me in a better place.’ (Service user 10)

Some service users emphasised that they have understood the potential benefits of SP for themselves, for example pain relief, reducing medication intake, and improving mental health conditions, after the GP has pointed them out:

‘Yes, doctor (Name of GP) was really good, he explained about everything, he thought it would be good for me because of my anxiety and my depression (...) He sort of said, he said (Name of navigator) would sort out the mental health thing it was, and he said (Name of navigator) would help and she was really nice, I would like her, and I should be doing this because he did not want to give me any more tablets, too many, you know, so...Yes, he did not want to rap it anymore, so, that was him really who got me start. It made me think: Maybe this is good for me?’ (Service user 1)

The SP programme was contrasted favourably with what was possible through medication. Service users believed that SP, in contrast to medication, has the potential to tackle the source of the problems resulting in long-term benefits:

‘Well, I do not want to pop any more pills than I have to. I regard pills as a short-term solution and I thought this [*social prescribing*] is something more than a short-term solution. I mean happy pills might get me through the winter, but what then?’ (Service user 3)

In addition to affecting the uptake of SP in the consultation with a GP, perceived need seemed to promote the engagement in the first navigator appointment, too:

‘One, I know I needed help. And two, it is always good to go and get advice and see what is there really. Especially if you yourself had tried or you see that actually I am done, and I need help. So that is what made me come.’ (Service user 9)

‘Cause I had to do something. I can see myself (...) So that is what took me down to see the navigator in the first place.’ (Service user 10)

GPs’ emphasised that perceived needs and benefits are key factors influencing primary care patients’ decisions on whether they agree, or refuse, to be referred to SP. According to a GP, those patients who agreed to be referred to the programme believed that they need a programme like SP to gain control over their health and to improve their health, wellbeing, or other conditions:

‘They themselves recognise that in a lot of situations they need to do something themselves, rather than always relying on pills. I think patients recognise that. So, I think, a lot of them say: If I could do this or if I could do that I would feel a lot better.’ (GP 1)

As demonstrated by the following three quotes, all interviewed GPs reported that those patients who refused to be referred to SP believed that they don’t need it and won’t benefit from it:

‘I had one person who declined, the last person I told it to, she was a carer for a dementia men, she goes like: Actually I have things to do, they take me out. She actually felt that she did not need to [*get involved in social prescription*] because she is already doing enough other things and getting support from other areas, so she did not feel the need.’ (GP 1)

‘some people they are already doing this, they go to the gym, they do swimming, relaxation therapy, acupuncture. They say: We are doing these things already.’ (GP 2)

‘Often there is this: Oh no I don’t think I need that.’ (GP 3)

Programme design

Flexible and low risk intervention

SP, unlike medication or more invasive interventions, was perceived as a flexible intervention that is unlikely to have adverse side effects. The intervention's characteristics seemed to encourage GPs to offer SP to their patients as a non-compulsory, low risk option to improve their health and wellbeing, and to address their non-medical needs:

'I think it is a gentle persuasion, give it a go it cannot do any harm! And then they listen to me. So it is just a gentle persuasion. Because in a sense, you know medications have side effects but spending an hour with the navigator does not really has a side effect, you are not going to lose out, you might gain! Who knows? So I think you could gently persuade them.'
(GP 3)

'I ask them [*patients*] what do you think about SP? Then I put it in a different way. I sell it in a way that it is nothing to be afraid of... if you don't like it, stop it, and we stop it.' (GP 2)

It seems that the GPs' attitude and the perceived flexible and low risk nature of the SP programme encouraged patients' uptake:

'He [*the GP*] said, you give it a go. He says, if you don't like it, you don't like it and you stop. Just give it a go. So I did.' (Service user 1)

'Because I mean, I have got nothing to lose by seeing the navigator, if there haven't been anything and I hadn't felt it could work, I could always say: Well no thank you.' (Service user 3)

Initial call from navigators

Following a patients' referral to SP, navigators contacted referred patients by telephone to arrange an initial appointment held in primary care practises. The following quotes indicate that this pathway promoted the uptake of patients who forgot about SP or would not have made the first step to arrange an appointment with a navigator:

'I thought that was nice [*that the navigator called first*], because a lot of people, you know they don't follow up, so you are just left. And then you don't go in the end' (Service user 1)

'Oh, I forgot about it and then she [*the navigator*] called' (Service user 4)

Some service users reported that they did not fully understand the SP programme when they were referred by their GP. Receiving a call from the navigator provided patients with an opportunity to ask for clarification, which seemed to promote their engagement with the first appointment:

‘I asked what this is actually for. And then she [*the navigator*] said all we do is sit there, we talk, I find out if there is anything I can help with, any introductions, any particular type of group or anything you know associations that I could get you involved with or introduce you to (...) Yeah, and then I came here to the surgery.’ (Service user 2)

Free of charge

Service users have reported that they agreed to be referred to SP because the prescribed activities are free of charge for the time service users are enrolled in the programme:

‘I thought: It is free, I try it.’ (service user 4)

However, a GP reported that patients refused to participate in the SP programme because of its short-term nature with a limited number of free sessions (usually twelve session):

‘There were patients who said: ‘Is it going to cost me money?’ And I said: ‘It might cost you a small amount.’ ‘So, and after this finishes does that mean, would I get a discount?’ And I said: ‘Well probably not’. Then they said: ‘Well there is no point then.’’ (GP 2)

Patient expectations

GPs described SP as an innovative and new initiative in Luton. They emphasised that patients may not expect a referral to a navigator, as they are used to, and therefore expect, medical prescriptions:

‘Patients expect to be referred to an investigation, or a drug, not to SP!’ (GP 3)

SP involves the active engagement of people on a long-term and is based on the biopsychosocial model of healthcare, which in addition to biological factors considers the wider determinants of health (i.e. psychosocial needs, health behaviors). GP 3 emphasised that patients refused to be referred to the SP programme because they may perceive it as something ‘unusual’ (GP 3) and it may not be in line with their expectations of primary healthcare. The next quote illustrates that the deviation from the traditional biomedical model,

in which patients usually take the role of passive recipients and often take medication to achieve a quick fix of symptoms, may result in non-uptake:

‘I suppose it is something unusual and it is not what you expect (...) You know, you just want to go home, tell you got a prescription and that you will be better in a week. And this is not like that. This is long-term, it is not a quick fix. It is more about whole lifestyle changes and patients are actively involved. They need to do the work. And that is why they refuse to become involved with SP.’ (GP 3)

The last quote indicates that the societies’ entrenchment in the biomedical model of healthcare, in which the patient often is a passive recipient of a medical intervention, may create a barrier to patients’ uptake of SP.

Stigma of psychosocial problems

The Luton SP programme is designed to identify and address psychosocial needs of individuals that determine their health and wellbeing. GP 3 expressed the view that the society’s stereotyped views about mental illness and social problems was a reason for refusing a referral into the SP programme, as patients are afraid of stigmatisation:

‘very often symptoms that have an underlying psychological or social basis, I think the society, sadly, you know, the stigma pervades the whole of society and it is easier for people to acknowledge that you are ill if you have a physical label. And if you don’t have a physical label to your condition, you are viewed perhaps with not that much sympathy as others.’ (GP 3)

‘they [*patients*] are afraid of being stigmatised. They feel that in some way they have not created the social environment that maybe is best for their wellbeing.’ (GP 3)

Section 2: Adherence

This section provides the findings from the analysis of the service users’ experiences and navigators’ and GPs’ views of factors affecting the engagement of service users with follow-up appointments with navigators and the prescribed services (adherence). Five themes were identified: Navigator role, support, availability and accessibility of services, perceived benefits, and health and wellbeing.

Navigator role

Navigator approach

Service users emphasised that the navigators' person-centred approach facilitated feelings of trust, control, and readiness to reflect on their current circumstances and their non-medical needs. Service users reported that they engaged with further navigator appointments because they felt listened to and valued:

'She [*the navigator*] was really nice, not come over harsh or anything. So she comes over really, you feel like she does care.' (Service user 1)

'I mean she [*the navigator*] is very good, she sat down, she listened to everything I said, and from there she build up almost like a profile on me. So that she was able to say: 'Right ok, I have got this that could help, or what do you think to this?'' (Service user 2)

'I think when you... when somebody understands and listens when you talk, if he [*the navigator*] listens, and try to find out what it is you want, what would make things better for you, and then action from there. He was asking me what would help me. I think one of the questions he had ask me was what was I doing before or what would make me feel better' (Service user 9)

Service users consistently reported feeling at ease and relaxed with the navigators, which enabled them to open up to them:

'she [*the navigator*] kind of puts you on ease (...) as I said, she is very easy, she kind of relaxes me.' (Service user 1)

Furthermore, the service offered by the navigator was contrasted favorably with what was possible through the GP. Service users reported that, unlike with GPs, they felt able to discuss their feelings and poor wellbeing without being pointed to a medical solution to deal with the consequences of the non-medical problems:

'Social needs, mental needs, you know, just general back up in life in general. I never felt that I had that before this (...) I was able to open up to (Name of the navigator), I almost used her as a counselor if you like. If you go to the GP and you say, 'I am having trouble at home', they say, 'oh take this tablet or take this pill, oh you will be fine in a couple of weeks', or you

know, 'see what it is like and come back in a week time if it is not better'. I am on enough tablets, the last thing I want is more tablets!' (Service user 2)

Service users appreciated not feeling under pressure to agree to activities suggested by navigators, if they did not like them. The following quotes indicate that service users engaged with prescribed services because the navigator gave them the opportunity to choose which activity they would like to do:

'But it was my option to say, 'yes that is quite good' or 'no I don't like that one'. Nothing offended her [*the navigator*] either. If I said, 'no thank you', then this goes bottom of the pile and lets start again, which was great from my point of view because I could do what I really wanted to do!' (Service user 2)

'I said that I also want something sort of that occupies my mind. And that is when she suggested the art class, which has been absolutely brilliant and exactly what I wanted (...) and I explained on the physical side that I am severely limited. She printed out for me the gym programmes at the various health centres, so I could decide where I wanted to go.' (Service user 3)

The previous quotes indicate that empowering and actively involving service users in decisions on their onward referrals facilitated feelings of control. Feeling in control and free to decide in which service to participate, appeared to promote service users' adherence.

Moreover, service users appreciated that the SP service was tailored to their individual needs, and that they did not feel pressured to engage with services if they did not feel ready to do so:

'I was due to go to counselling but at the time it was not right for me. I phoned (Name of navigator) and I said, 'I am sorry I can not do it.' And she said 'it is for you for when you are ready. You do not have to go, it is not mandatory that you go, just because you said it, does not mean you have to go.' (Service user 1)

Navigator turnover

In the Luton SP programme, navigators have left the programme before new navigators were employed and ready to takeover the role. These gaps between navigators prevented a smooth handover of the navigator roles and service delivery. Service users reported that they have stopped engaging with the SP programme because they couldn't contact their navigator anymore:

‘I tried to call her a lot, she didn’t answer the phone and then I found out that she left the surgery. And then from the surgery reception they said that there is a new navigator. But I have stopped already.’ (Service user 7)

A service user reported that some service users stopped engaging with an art group because their navigator has resigned from the programme. Service user 3 expressed the view that the relationship and trust between navigators and service users is a crucial factor affecting the adherence of service users:

‘Yes. She left. Which has left us a big gap (...) And even though the other navigator could do certain amount, because she hasn’t had the in depth talk with them, like she had with me. They did not know who to talk to really and stopped coming’ (service user 3)

Support

Family and friend support

Navigators emphasised that the support of family members is a key determinant of initial service user engagement in services:

‘But then, sometimes if they [*service users*] have someone to support them they will go, so it is individual. I had one lady, whose daughter is determined to that lunch club, and she is ringing me, she was asking me where it was yesterday, she is very passionate about it. The patient has said, ‘yes I will go’, but that family member is the key there, it is the key to get that patient there.’ (Navigator 1)

In line with the navigator’s perception, service users reported that the support of their family and friends encouraged them to engage with the services:

‘But now I am going [*to the gym*], my son did say to me, ‘Mum just go, you will be alright.’’ (Service user 1)

‘But I get a lot of positive support from my family, saying they are so glad that I am doing this and all that sort of stuff. And in fact, a friend of mine one night said, he was proud of me!’ (Service user 10)

Service users who aimed to lose weight and to live a healthier lifestyle emphasised that it was particularly helpful to continue engaging in physical activity and improve their diet, if family members and friends followed similar interests:

‘I try to go three times a week (...) My wife is going to the gym and my son is going to the gym as well (...) and Tuesdays I try to go after work with my colleague.’ (Service user 10)

On the other side, the next quote demonstrates that the absence of support from family members and friends can foster service user disengagement:

‘Oh, we never actually took it on (...) I couldn’t motivate my husband to go, I didn’t want to go by myself, I couldn’t find somebody else to go. I just didn’t want to go by myself.’ (Service user 4)

Navigators highlighted that, within their job role, they can remind service users of the activity a day before and meet them at an activity to support them. However, as they cannot physically take a service user to an activity, having family members and friends who encourage and support service users to take the first step, i.e. going to an activity, was crucial:

‘and often people do not have that [*support from family and friends*], so it is very difficult. And I can’t take anyone anywhere, so I can meet them there, but then they are already there. So if your difficulty is getting someone there (...) it becomes harder.’ (Navigator 1)

Navigator support

Service users repeatedly reported that the support of and work with the navigators facilitated the feelings of readiness to engage with services they would not have engaged with otherwise:

‘And she [*the navigator*] helped me quite a bit actually. She has been very good actually, I went to the gym this morning. There is no way I would have gone to the gym without her. No way I would have done it!’ (Service user 1)

‘I don’t think I would have gone to the gym. I couldn’t even tell the last time when I was going to the gym before this. I couldn’t tell you, phhhfff, no. It was seeing (Name of navigator)...that helped me to do the first step.’ (Service user 10)

A central part of the navigator role is to provide on-going support to service users to facilitate adherence to services. Navigators emphasised that they needed to work with most service users to address potential barriers to engagement and adherence, such as low self-confidence and mental health issues. The level of required support varied among service users, however, it appeared to be frequent practice to work with service users to overcome barriers to adherence, before referring them onwards:

‘there is a little bit of early work to do before they actually go out to activities, around mental health and wellbeing, that possibly was a little bit underestimated when we first started. So there is a lot of mental health kind of getting them ready for SP, as opposed to straight into SP.’ (Navigator 2)

‘Then I meet with them [*service users*], have an appointment. I would always suggest something in that appointment, a referral, a service, a way that we can help, but it is very rare that the patient then goes of and uses that service straight away (...) It is very rare that I refer someone and they go off and I don’t hear from them.’ (Navigator 1)

Navigator 1 stressed that some barriers to social engagement, for example low self-confidence, are likely to exist if a service user feels socially isolated. Hence, addressing the potential barriers to engagement in a social activity first is required to facilitate engagement and adherence to referred social activities. To support service users, navigators reported to use a two-step approach, in which the first activity supports and prepares the service user to engage with further activities addressing the non-medical needs:

‘But often, if the outcome for them [*service users*] is social engagement, obviously there is a big barrier there and that is not going to be easy to send someone straight into a group like that. So often they need some work, for example a massage therapy first, to make them feel better before they can go and do something like that. Or they need counselling, or they need to see the mental health worker at the surgery, or they need to look at their medication perhaps, or some things. So it is looking at the barriers to that before. Often it is not worth sending someone straight into that situation before addressing what is going to prevent them.’ (Navigator 1)

Service users appreciated that face-to-face contact with navigators was also supplemented by telephone, email, or text. Knowing that the navigators were there for service users while being enrolled in the programme, and especially if they needed help, encouraged service users to adhere to the programme:

‘I know as well that I can phone (Name of navigator) up at any time and she will try and sort something out for me. Definitely to think that, you know, I have got someone on the end of the phone, that helped to feel that I am not alone (...) I can cry down the phone, or you know, whatever, but she is always there.’ (Service user 2)

‘I go [*to the gym*] because I know if something did go wrong, you know I can ring her [*the navigator*]. I have her number and she said that I could, if anything, just give her a ring anytime.’ (Service user 1)

The level of support that service users required in order to engage with services was dependent on their individual needs. Navigators believed that accompanying service users to first sessions, and helping them to build confidence, self-reliance, and eventually independence were crucial steps determining the adherence of some service users:

‘you have given them the confidence and you might even have helped them go by taking them and holding their hand, introducing them, be there for a couple of sessions with them’ (Navigator 2)

In line with the navigators’ perceptions, service users have highlighted that without the navigator’s accompaniment, they would not have engaged with agreed services and activities:

‘Like she said, ‘if you want I could come’, you know, she sort of like said she can come so I feel better. To the gym, she said she could come up there for my first one...that helped cause I was terrified...gym...uhhhr’ (Service user 1)

‘I still want to say thank you to her, when she booked me in to go to the (Name of organisation), I said to her, ‘I want to go but I can’t’. So she said, ‘why not? Is it the timing?’, I said, ‘no, no, no, physically, I can’t make that step forward’. So she agreed to meet me at the clinic, which was amazing. Nobody has ever offered to do that before and it was absolutely incredible (...) I cried, I had a massive panic attack, standing in front of the door (...) And she said, ‘I am here.’ And I remember her putting her arm around me and saying (...), ‘I am with you, I will come upstairs with you, I will sit with you’ and for me that meant a lot (...) And I seriously needed that (...) I could not have done it without her.’ (Service user 2)

It is interesting that the experience with the navigators built the confidence of service users and supported them to adhere to services on a longer term:

‘She sat next to me and said, ‘come on you can do this, only other women, no men allowed in here, and they have all gone through this’, and it was...yeah ok. And then when I went the second time, I remembered that and then I just grew in confidence.’ (Service user 2)

Service provider support

Service users reported that they have not received a response from service providers after being referred by the navigator:

‘I have not heard anything from them. I am surprised cause they said they would ring me or text me for another appointment, but I haven’t heard nothing since.’ (Service user 1)

‘I left a voice message, I called again, I had someone on the other end, they said they will call me back. They never did.’ (Service user 6)

The next quote demonstrates that not hearing back from service providers for a couple of weeks delayed service users’ engagement with referred services:

‘So because (name of organisation) didn’t contact me for a couple of weeks after she [*the navigator*] referred me, and she said they will contact me in this time. They didn’t contact me, so then I have to phone the surgery and I have to book an appointment with him [*the navigator*].’ (Service user 8)

One service user reported that she did not engage with the referred services at all because she hasn’t received a response from the service provider regarding an appointment:

‘But I haven’t actually done anything, but only because no one would get back to me. At the beginning it was great, everyone was contacting me back, and someone came to go through it.’ (Service user 6)

In addition, some staff, for example gym instructors, who provided services to service users did not understand or were aware of the SP programme:

‘No, and they [*the service provider*] gave me a hard time. He [*trainer in the gym doing the induction*] kind of said, ‘well nothing is free’, and he went on. It was a bit abrupt for a personal trainer (...) He said, ‘what is this?’, because my card has written social prescription and staff like this and he is like, ‘do you pay?’, and I was like, ‘well, I don’t personally pay but it is through this social prescription’, and then he is like, ‘I don’t know what that is, I need to find out what that is’. He was quite abrupt about it.’ (Service user 9)

The following two quotes demonstrate that the lack of service provider's understanding of the SP programme, and consequently the lack of support for service users, have unsettled and discouraged service users to continue engaging with the referred services:

'He [*gym instructor*] was like, 'nothing is free', kind of thing. And I was like, 'I know nothing is free, but I am here through social prescription'. But I think maybe what he must have wanted is for me to pay him or one-to-one personal training (...) But I think it would definitely help if he [*gym instructor*] would knew what social prescription is, not to feel the embarrassment that you are doing something wrong. I wasn't sure I wanna go again, but now I am ok.' (Service user 9)

One service user explained that she stopped engaging with a meditation class because the service provider did not show up to the class and classes were cancelled on a frequent basis:

'I did go for few more sessions, but it got sort of, there were couple of times that I came down for it, and she [*service provider*] wasn't here. And at other times, I get a phone call that they double booked the room. So it started to get a bit sporadic, and I think I just got out of think with it.' (Service user 4)

On the other side, service users felt encouraged to engage with services when service providers welcomed them and were supportive throughout the activity. Service users reported feeling comfortable and at ease with service providers. Developing an open and trusting relationship between service providers and service users promoted adherence to activities:

'Yes, so I knew someone was waiting for me (...) Yes, I would just sat and waited at the table, and she picked me up.' (Service user 1)

'she [*gym instructor*] is always about, she is in there, so I am not alone. It is not like she is not there, she is there (...) and she is... kind of helped me, and I think, I just sort of know her. And I was quite comfortable with her today (...) She is supportive.' (Service user 1)

Availability and accessibility of services

Service users emphasised that they did not participate in the referred services because the days and times the activities took place did not suit their schedules:

‘Because I finish work at four o’clock, and they [*the service provider*] were like three [*o’clock*]. I was like, I would need to leave work at half two to get into town at three, it is just not, there is no way my boss will let me of half an hour every week.’ (Service user 6)

‘It is understandable that they cannot do it between eight and five because it [*the pool*] is used by the school, but they could run a session at seven in the morning for people to go to before work (...) Or they could do Saturday or a Sunday, there is no Aqua fit at the weekends. I would be quite happy to go on a Saturday or Sunday morning. It is just that by seven thirty in the evening, I can hardly go, because I wake up so early.’ (Service user 3)

Navigators expressed the view that in addition to availability, the accessibility of services is a key factor determining service user engagement. Language barriers, financial constraints, feeling uncomfortable to leave the area, or dependency on family members to leave the house were mentioned as potential barriers to access services:

‘For example the Massage service is in (Location), which is 10 minutes drive. It is limited to who I can refer to that because I know that that may make it very difficult for patients to get there. There are busses, but if they don’t speak English or they don’t have any money themselves, so the husband might manage the finances, or they don’t leave the house unless a family member comes for them (...) So, transport and money are issues.’ (Navigator 1)

In line with the navigator’s perception, service users stressed that barriers to access the referred services hindered their adherence. The following six quotes demonstrate the barriers to access services, experienced by service users.

1) Dependency on family members or friends for a lift and financial constraints:

‘I go anytime I can find a lift. Before it is like, when the navigator referred me on that time my sister in law go there, I went like three times a week. Yeah, but she is now ill and then whenever my husband is off he can give me a lift or my friend.’ (Service user 7)

‘from where I live it is quite a walk and for the busses and staff like that, they charge a lot money, I can’t afford that’ (Service user 7)

2) Feeling uncomfortable to leave the area:

‘I never done it by walking. Because it is quite up, it is next to where dead people are buried. I didn’t went by walk but it is quite difficult to walk through (...) I don’t feel comfortable with the way, it is quite difficult I never went there, I don’t know whether it is a one hour walk or what it is’ (Service user 7)

3) Services are difficult to access with public transport and too far to walk:

‘there is a lady who works for the community something, so she said you can come but the problem is that it is far away, and the bus doesn’t go from my house to (Location), I need to walk through the park and then I have to take the bus or maybe walk, it is far away for me.’ (Service user 8)

4) Time consuming to get to service:

‘But the day time class is right across the other side of town, in (Location), which is about 25 minutes drive away. So, it is not ideal at the moment.’ (Service user 3)

5) No parking possibilities in near surroundings:

‘there is no way to actually park. Trying to cross the A6, I am sorry, you can’t expect a lady about 70 years, on a stick, to leap across traffic doing 40 mph, I am sorry, no way.’ (Service user 3)

Experienced benefits

Those service users who experienced benefits from participating in SP reported that this experience affected their adherence. The following quotes demonstrate that a wide range of benefits were experienced by service users, including socialising, pain relief, relaxation, fun, feelings of accomplishment, and improved mood, which promoted adherence:

‘The gym was funny, I thought I hate it but I like it, so I kind of can’t wait to go.’ (Service user 1)

‘And we chatted while we were working and we laughed a lot. And someone might be, that might be the only time all day that they laughed. So, there was a benefit to what we were actually doing and there were the benefit of being part of the group as well.’ (Service user 3)

‘[I continued] because I could feel that it was definitely helping, pain relief, relaxation.’
(Service user 4)

‘And it felt amazing. Absolutely amazing. And it was almost like that is why I went there, to say, yes I could do this.’ (Service user 2)

In addition, service users highlighted that the internal and external reward of doing an activity, which they don’t get from taking medication, was a reason for their on-going adherence to prescribed services:

‘how can meds [*medication*] give you the reward you get from painting some little birds on a bird house, and thinking, you know if I saw that in a shop I might buy that. That is not bad. So you have got the benefit of having had the enjoyment of doing it and then the pride of having done something that is actually decent.’ (Service user 3)

‘It lightens my mood, definitely. It is much better than taking a pill. I wake up on Wednesday and I think, good it is the art class today.’ (Service user 3)

On the other side, those service users who believed that they could not benefit from the referred services, stopped engaging with them:

‘they [*service provider*] said, like, ‘what is the problem’, and I said to her, ‘I am having this housing problem’. They said, they can’t help me, so there is no point in going there. Yes, so they said they can’t help me, ‘if you ever want to share any problem you can come here’, there is a women session or something. I said, ‘I am having pain and the housing problem, I don’t want other things.’’ (Service user 8)

Health and wellbeing of service users

Navigators expressed the view that in some cases service users’ non-adherence was also related to their mental and physical health issues, wellbeing, or drug misuse:

‘I think some people just don’t have, depending on what their problem is, their physical their mental health problem, they go through stages where they just don’t want to engage, they don’t answer the phone because they are unwell.’ (Navigator 1)

‘So they [*service users*] are non-compliant because either they have got alcohol and drug misuse of some description, or they have injuring mental health problems that may have escalated and they have gone into secondary mental health, so sometimes they have been sectioned or they have been in hospital.’ (Navigator 2)

In line with the navigators’ views, service users have reported that their health problems and poor wellbeing has hindered them in engaging with prescribed activities:

‘At the moment I don’t dare [*to swim*] because I am still having dizzy spells, I am a bit dizzy, I mean I can swim but ...’ (Service user 3)

‘I didn’t go [*to the art class*] because of my asthma, if I get any sort of a cold or chest problem, it gets magnified, every so often. If I slept awkwardly or something my back is really bad and it hurts to walk, I can’t sit. So, [*missing a session*] only because of health issues, no way because I didn’t want to go, because I couldn’t go.’ (Service user 3)

‘I don’t feel like going out, because if I walk a little bit... You know it looks like I am... you know, nobody can tell that I am disabled and can’t do nothing but it is painful, it is really painful.’ (Service user 8)

8.3.3 Summary of findings

The first section has presented the service users’ experiences, as well as navigators’ and GPs’ views of factors affecting the uptake of the Luton SP programme. GPs’ navigators’, and service users’ expressed the view that patients’ trust in their GPs, who make the referral to SP, promoted patient uptake. In contrast to this general perception, one GP highlighted that patients may refuse to participate in SP because they trust their GPs explicitly, and therefore would not participate in services beyond their GP’s care. Realising the need for SP and understanding its potential benefits for patients was another identified factor promoting uptake. GPs emphasised that not perceiving the need for SP was a common reason for non-uptake. Patient uptake was also related to the way the programme was designed and structured. The free, flexible, and low risk nature of the programme, seemed to promote patient uptake. However, GPs reported that the short-term nature of the programme and limited number of free sessions were reasons for non-uptake. In addition, GPs identified patient entrenchment in the biomedical model of care and fear of stigmatisation as potential barriers to uptake.

The second section has presented the service users' experiences, as well as navigators' and GPs' views of factors affecting the adherence to the SP programme. Service users found the navigators' person-centred approach, active listening, and good communication skills to be key in aiding their on-going adherence. Furthermore, feeling at ease and relaxed with the navigator enabled them to develop a trusting relationship, which was perceived as important by service users. Empowering and involving service users in decisions about their onward referrals helped service users to feel ready and able to engage with activities. However, the disruption of a smooth service delivery, due to navigator turnover, resulted in non-adherence, and in some cases to the dropout of the programme. On-going support from family members, friends, navigators, and service providers were identified as key factors determining adherence. Experiencing benefits, such as pain relief, relaxation, or mood improvements, as well as internal and external rewards from activities were identified as key motivators promoting adherence. Some service users perceived the availability of services, for example during office hours only, as a barrier to adherence. Costs of public transport, dependency on family members and friends to leave the house, and unfamiliar and difficult to reach locations were mentioned as barriers to accessing services. Finally, service users' poor mental and physical health, including mobility issues and pain, were mentioned barriers to on-going adherence.

8.4 Objective 4: Service user outcomes

8.4.1 Participants

The same service user sample was interviewed for objective 3 and 4 of this study. The characteristics of interviewed service users are summarised in Table 13 and Table 14 (section 8.3.1).

8.4.2 Findings

This section provides the findings from the analysis of the service users' views of outcomes of the SP programme. Three themes were identified: Health related behaviours, mental wellbeing, and pain relief.

Health related behaviours

Many participants attended physical activity classes, specifically tailored to their health needs and level of fitness. Service users noted that the physical activity related lifestyle changes resulted in weight reduction, functional improvements, increased energy, fitness, and motivation, feelings of happiness, and improved mood:

‘now small everyday life things work better, I can put my socks on. And I can see a slight decrease in my waist’ (Service user 10)

‘with the personal trainer I do gym at the same time, I lost one stone in a six week time.’ (Service user 7)

‘In the morning I would wake up and just feel, you know, my mood was really really low. But knowing that you got yourself to the gym and you have done it, it is quite exciting, it makes me happy. And it is more, I have got more energy for my son as well’ (Service user 9)

Service users often reported that their physical activity related lifestyle changes had a positive impact on their diet, as they were motivated to eat healthy food after they were physically active:

‘I feel good, I feel tired, but I feel good after it [*the gym*]. When I come back, I try to have healthy food, this is not good for me because I did all the hard work, so how much calories does this have? What is the point in eating this because I just did all the hard work in the gym’ (Service user 7)

‘A 100% it [*the physical activity*] helped me. Especially being more active now. It is everything, physical, mental...once you go to the gym and you work out you just come out feeling lighter, feeling happier, you are more active. I want to cook, whereas before I just couldn’t be bothered to do anything’ (Service user 9)

However, some service users who were referred to physical activities and social/creative/support activities tended to engage with the social/creative/support activities, while not attending the physical activities. Therefore, service users who were aiming to improve their health related behaviours not always achieved this aim:

‘So for me the benefit has been much more on the artistic creative side than on the physical side’ (Service user 3)

‘Oh, we never actually took it [*physical activity*] on. I still have the card [*for the gym*] in my bag, I don’t even know if it is still valid.’ (Service user 4)

Participants who received healthy eating advice described in some detail how they have reduced their intake of unhealthy food and how they were equipped with practical skills, for

example understanding the nutrition label system, to manage their weight and incorporate healthier foods in their daily diet:

‘I don’t eat as many sweets as I used to. I eat nuts now which (service provider) put me on to (...) I only eat brown bread now, try to only eat brown rice, and whole wheat pasta. Try to change the dietary habits. We used to eat white bread, white rice, wheat, and pasta... and then the amount on a day.’ (Service user 10)

‘I was drinking a Budweiser and I was looking at the calories on the bottle. It is over a 100 calories in a bottle of Bud [*Budweiser*], I think I drunk three or four. And at four, I am like, that’s it....I got to burn that off somehow. And before I would have stopped drinking at four in the morning. I am looking at things like that differently as well.’ (Service user 10)

Service users found the navigator and service provider to be key in achieving positive health behavior outcomes. Specifically, the service provider’s and navigator’s personality, professionalism, support, and motivation were highlighted:

‘she [*the navigator*] is really nice, had time to actually sit and it wasn’t a 15 minutes appointment. Less rushed. That was when I started to go to the gym properly and to swimming as well. She sort of encouraged me. And motivated me to go, to do it.’ (Service user 6)

‘I thought the whole experience was really good and I can’t praise (name of service provider) enough. We talked about our children or whatever while I was exercising and the time went on quicker. He motivated me and all that sweat was pouring out of me (...) I also really feel he cares, he said to me because of my lungs, ease up a little bit because I can hear you are struggling with your breath’ (Service provider 10)

Moreover, the statement in the previous quote ‘had time to actually sit and it wasn’t a 15 minutes appointment. Less rushed.’ (Service user 6), indicates the importance of factors such as time and space for service user outcomes.

In general, those service users who at the point of the interviews were enrolled in a physical activity had plans to continue being physically active beyond the SP programme. Some service users had made very detailed plans, including cost calculations and time management, whereas others have not thought about the execution of their plans at this point in time:

‘I will continue. One of the things is, my son is paying at (name of gym), I think he is paying 36 pounds a month. Then we will get a joined membership together and that will be then 50 pounds for the two of us. So it is 25 pounds each.’ (Service user 10)

‘I will need to think about something. I will try and budget in a bit more because what happens when you get student loans in the summer it finishes, so I was put on like income support, so that would not stretch at all. So maybe when I get my student loan, I would have to budget in, maybe a cheaper gym, I need to try and find one.’ (Service user 9)

However, the reported health behavior changes appeared to be strongest while service users were enrolled in related activities. Service users reported that they have gained weight back and fall back to old dietary habits, once they finished the set of referred activities:

‘I mean I have been with (name of service provider) for four months, I lost about a stone and three pounds. I think, I put a couple of pounds on the last couple of weeks because of binging [*binge eating*] and without the support of (name of service provider).’ (Service user 10)

‘I done so much exercise and control my food and lost, I recently lost, go back to 65 [*kg*], and then I did go back to 69,7 [*kg*] again today, within three weeks. It go back quickly, like you know, I tried to maintain it, but I can’t you know.’ (Service user 7)

Financial constraints to continue prescribed activities after the end of SP, and the lack of motivation, control, and space to maintain behavior change by oneself, were mentioned barriers to continuing physical activities and the intake of healthy food:

‘The reason why I closed it [*the gym membership*] is that they charge a lot. They charge 22,99 [*£*] per month, and plus joining fee and cancellation fee, and when you freeze it they charge half money for that as well (...) I am not do the work, I don’t work, I am carer with my mother in law (...) it is too expensive my husband said you know.’ (Service user 7)

‘At the moment, I don’t think, I am not sure what I could do by myself especially in the space I am. I have got half this size [*of the room in which the interview takes place*], for just me and my son. So there is not much I can do, unless I go jogging. But I just don’t feel as motivated to go jogging, like when you go to a gym and there are people around you - the atmosphere is different.’ (Service user 9)

Mental wellbeing

Participants commonly experienced depression, anxiety, low mood, stress, and social isolation. Most participants reported that their mental health problems and poor wellbeing were related to a combination of physical health, personal, psychosocial, and economic factors including job loss, housing problems, relationship breakdowns, bereavement, alcohol abuse, mobility issues, fear of stigma, health conditions, bullying at the work place, financial problems, and homelessness:

‘I too put on weight when I lost my job, and that did not help. That depressed me. So things like that, just spirals, one thing leads to the other.’ (Service user 1)

‘The problem is that I cannot stand for long time, and I cannot walk a distance because of the back, the knees, because of the asthma. So things that I might have wanted to take up haven’t really being practical and I found myself more and more sort of retreating into just sitting and watching the TV, consequently drinking too much wine. And I could feel myself going into a sort of downwards spiral, I gained weight ... and I was a bit depressed’ (Service user 3)

One of the interviewed service users felt that she hasn’t experienced any positive impact on her mental wellbeing. She reported that besides the navigator’s attempt, her housing, financial, functional, and social problems, impacting negatively on her mental health, were not solved:

‘So, she did refer me to a couple of places, we had a meeting, we involved a social worker and then some other people as well, I forgot the names, and then yeah, we had a couple of meetings, family workers from school, from nursery from my daughter, we all were involved, we discussed our problems, my problems, and then nothing happened in the end.’ (Service user 8)

Other participants experienced outcomes, such as improved mood, increased confidence, self-value, and motivation, and reduced social isolation, which positively impacted on their mental health and wellbeing. These outcomes will be explored in the following section. However, it is important to note that besides the benefit of the content of the referred sessions, usually provided by third sector organisations, service users highlighted that the navigator’s and service provider’s personalities and approaches were key for improving their mental wellbeing:

‘I was able to open up to (name of navigator). I trusted her, and felt ok to kind of, you know, to unravel all my problems, so that we could find a point to start. You know, I would not be where I am now without the support from (name of navigator)’ (Service user 2)

Mood

Service users who attended counselling sessions, creative, and physical activities reported that their mood has improved, which also had a positive impact on their relationships with friends and family members:

‘It lightens my mood, definitely. It is much better than taking a pill. I wake up on Wednesday and I think, good it is the art class today’ (Service user 3)

‘it has improved the relationship to my wife, I think that has improved because I am not so miserable. And probably with my children as well, because I am not so miserable.’ (Service user 10)

Participants have not only attributed their improved mood to the referred activities but also to the sessions with the navigators:

‘The sessions [*with the navigator*] took of a little bit of, I wouldn’t say I was depressed, but I was a bit down. It did help, just having someone to listen. My mood gets better because someone actually just set there and gone, ‘you are not being silly’. It was just inside.’ (Service user 6)

Self-confidence and self-value

Service users reported that through the work with the navigator and participation in referred activities (physical, creative, social, and advice/therapy) their self-confidence has increased:

‘I have gained confidence to the fact that I take myself to the gym and have actually realised that the gym is good for me.’ (Service user 10)

‘I am a lot stronger. I am a lot stronger. I no longer put physical barriers on myself, I would try something first, which I never had the confidentiality to do before (...) I have gained so much confidence’ (Service user 2)

As service users grew in self-confidence, they were willing to try new activities, such as yoga, Thai Chi, and aqua fit, and to participate in community events. None of the participants

considered engaging with any of these activities before participating in the Luton SP programme:

‘What the (name of creative activity group) has proved me is that I could do things I didn’t think I could do and even when I don’t think I would enjoy them, when I get there I do. So that gives me the incentive to look for more things.’ (Service user 3)

‘I want to have a try with this [*aqua fit*] as well, but before this [*social prescribing*]...No way. No way to go ...too embarrassed, like swim suits they are uhhh, but you know, way to embarrassed, no no way!’ (Service user 1)

A service user who attended a women group reported that listening to similar stories and sharing experiences helped her to improve her self-value. She stopped feeling stigmatised, a feeling she has lived with for the past twelve years:

‘They [*the women group*] made me feel that not everyone is pointing at me or laughing at me. I am not the only one going through everything (...) it helped me to get out of this stigma of when I walked down the street people are not staring at me. I haven’t got a label above my head that I thought I had.’ (Service user 2)

In general, service users reported that they apply the skills learned in the SP programme to various situations in their daily life, making them feel more confident. There was an agreement among participants that they will continue using their acquired skills independently from, and beyond, the SP programme:

‘Oh no, just because I don’t come like every fortnight, so that is over, I am not. I go on with the skills I learned.’ (Service user 2)

‘I am more confident in the gym and I learned talking to complete strangers and be around people, so now I can go out to town. Once I feel confident here, I will try another town, then maybe go to London, and so on. I will use the skills I learnt to go on, but you know baby steps’ (Service user 1)

Motivation and new hobbies

Many participants have reported that they have not had a hobby and lacked motivation to perform any leisure activities before they participated in SP. Their daily routine comprised of staying in the house, watching TV, and doing the housework:

‘I never had a hobby. It was one of those get up in the morning, make lunch, clear up, make tea, clear up, watch TV. For years and years and years I have done that. I just wasn’t motivated to do anything else.’ (Service user 2)

Service users highlighted that through the referred physical and creative activities they have learned new things and refreshed or developed new skills. Furthermore, participants felt motivated to do things, for example decorating the kitchen, painting on pots, glass, or wood, creating cards, going to the gym, or joining a community activity or running group, rather than watching TV and being inactive:

‘I never painted on glass before *[SP]* and I really like painting on glass. I have got this collection of empty yards waiting to be painted. So that is the next project. Instead of sitting and watching something I don’t really want to watch’ (Service user 3)

‘I was fed up with the kitchen so I just painted it and decorated it, so things like that I would not been interested in before. I had no go in me. I just wanted to sit around and watch the TV’ (Service user 1)

Service users reported to learn to use creative and physical activities as coping mechanisms to make them feel better:

‘when I am not particularly well on a day, it is a way to cheer myself up. I go and get the bands, just get some rocks or something to paint them, get some cheap terracotta pots’ (Service user 3)

‘But you don’t get treated as a great teacher, you are treated as rubbish. So that doesn’t help, its just making me feel down. And then I go to the gym and let it out.’ (Service user 10)

All participants who discovered a new hobby stated that they plan to continue performing their hobbies, beyond the SP programme, in the future:

‘I have now started doing things at home. Which I would not have done if I haven’t gone to the art group. So that is a definite change.’ (Service user 3)

Feeling able to afford the continuation of the new hobby, seemed to affect its continuation:

‘material is not expensive because a lot of what we are doing is, you know, you go to Poundland and buy some cheap terracotta pots and so on, it is not expensive, we don’t need a lot of gear to do it. Money is not a problem here.’ (Service user 3)

Social contacts

Offering service users activities that allowed meeting people and socialising in the community reduced social isolation and positively impacted on their mental wellbeing:

‘It gets me out of the house. Gets me chatting to people I would have never met otherwise and we have fun and we laugh.’ (Service user 3)

‘It does help a lot with my depression and anxiety, like I said, I got more going now. Before I would not do anything just sit in the house (...) just really I get panic attacks as well, I can’t breath, I think I am dying. And you know it [SP] helped with that a lot. The whole social thing again, mixing with people, I would not do that before.’ (Service user 1)

Service user 3 contrasted SP positively to medication. She believed that medication to deal with her depression would not have changed her behaviour and the fact that she was socially isolated:

‘And sometimes I need forcing it out, and I think if you gave me pills, all I would be doing is exactly the same but with the pill whereas this has forced me out and to meet people’ (Service user 3)

However, service users expressed the view that the short-term nature of the programme (12 sessions) is not suitable for everyone. Service user 3 expressed concern about another service user, whose only time to socialise and meet other people was during the SP related creative activity. It was emphasised that stopping an activity after 12 sessions may have a negative impact on someone’s wellbeing on a long-term, just as stopping an antidepressant abruptly:

‘she is emotionally very fragile, and she told me, that that is the only time in the week when she goes out, when she goes to the art class (...) And I am worried that she had twelve weeks were she had come out of herself a bit, and she was a bit better. And if it stops, I think she could end up worse than when she started. I think that is one of the problems about saying, ok, you have got 12 weeks and then it is over.’ (Service user 3)

‘before you just say stop, you need to look at the people involved because some of them might need quite careful after care. You don’t just give someone Prozac [*an antidepressant*] and then stop it, do you? So I think you should look at social prescription in the same way.’ (Service user 3)

Stress

One service user reported to feel stressed all the time, as she cares for her mother and husband, both having mental and physical health problems:

‘it is not just going down there to help her, it is all the other things, all the phone calls, I am in charge of financial affairs, making sure she has enough in the bank to cover her care fees. It is a lot, not only hands on, it is also when I am at home as well. And then my husband, he has mental health issues as well, so I look after him’ (Service user 4)

During a meditation class she learnt how to apply mindfulness techniques to relax and deal with daily stresses:

‘It helped me mentally...a lot! I now find that I can relax. I know now what to do, like concentrate on each area of the body’ (Service user 4)

Service user 4 noted that as a result of regular meditation at home, after completing the SP programme, her stress level has decreased and she felt more energised:

‘Maybe about two, three times a week. And I feel a lot better, less stressed. I think sometimes I do actually go in a sleep, and then I feel like I had a good night sleep and it is not night time. I have a lot more energy then to carry on what I am doing.’ (Service user 4)

Another service user reported to feel stressed and down all the time because of her inadequate housing situation with her two-years old son. Being signposted to a housing charity has helped the service user to speed up the process of finding an appropriate accommodation. Receiving housing advice resulted in stress reduction and positivity:

‘I am still there, but at least they have made a decision that, yeah, they have a duty to me, and I am sure some things will be done soon. I am more positive now, less stressed, thanks to (the navigator’s) help’ (Service user 9)

Pain relief

Massage therapies are part of the activities navigators could refer service users to. Interviews showed that massage therapies had both a positive impact and no impact on a long-term. One service user who stated to suffer from shoulder pain for the past five years, besides trying acupuncture and physiotherapy, reported a long-term pain relief:

‘I have had a bad shoulder for years, at least five years. I have had acupuncture, I had physiotherapy. I have done the exercise the physio gave me, temporary relief only (...) I had 18 weeks off work because of my shoulder.’

For service user 4, the so-called ‘holistic massage therapy’ resulted in long-term (six months) pain relief:

‘My shoulder, it has been six months now since I have had the massage, and my shoulder is still pain free. I couldn’t do that [*moving arm up and down*] before, it hurt too much.’
(Service user 4)

Being pain free facilitated her daily life, enabled her to sleep, and stopped the intake of painkillers. Another service user (service user 5) experienced a pain relief in her lower back during the first 12 massage sessions. Being pain free in this period resulted in feelings of happiness, weight loss, and motivation to get going in the morning:

‘I am feeling very happy and I told her [*the navigator*], you know when you are in pain you don’t like to dress up you don’t like to do anything, but when you are really ok, your back stop pain, really happy, you dress up. It makes changes your life and it encourages me to lose, I was 101 kilo because I sit here I couldn’t move, so it helped me within two months, I have reached to 92 [*kg*]’ (Service user 5)

However, at the point of the interview (three weeks after the massage therapy) the patient experienced strong pain in her lower back and reported to feel sad, depressed, and physically disabled:

‘now I have not been for a while, more than three weeks and I have the pain from the beginning of the months, severe, severe, severe, you couldn’t live’ (Service user 5)

Financial constraints were mentioned as a barrier to continue the massage therapy beyond the SP programme:

‘Because I can’t afford to pay the 42 pounds just to do one session of massage, because I am not working. I came here in this country as housewife.’ (Service user 5)

8.4.3 Summary of findings

This section has examined the service users’ views of outcomes of the SP programme. Health related behaviour changes, including physical activity and a healthier diet, were reported outcomes for service users who attended physical activities and nutrition advice classes. Although all participants planned to maintain their lifestyle changes, it seemed to be challenging to maintain physical activity levels and healthy eating habits once the referred sessions under the SP programme were completed. This study also found that participation in physical, social, and creative activities, as well as counseling sessions, resulted in new hobbies, improved mood, self-confidence, self-value, motivation, as well as reduced social isolation and stress, which positively impacted on service users’ mental wellbeing. Service users reported to apply the acquired skills in their daily life, for example to manage their stress, beyond the SP programme. Massage therapies resulted in both long-term (six months) and short-term (three weeks) pain relief. In general, service users reported that the personality and support of the navigators and service providers was key to achieve positive outcomes. Only one service user with housing and functional issues, pain, stress, and social isolation did not experience any positive outcomes from the SP programme.

8.5 Chapter summary

This chapter presented the qualitative findings of objective 2, 3, and 4. Many factors that hindered and facilitated the implementation of the Luton SP programme were presented (Objective 2). These factors tend to be interrelated. For objective 3, different factors that affected the patient uptake and service user adherence were presented. In addition to the doctor-patient, navigator-service user, and service provider-service user relationships and encounters, personal and contextual factors were found to influence the uptake and adherence to SP. Lastly, a wide range of service user outcomes, related to health related behaviours, mental wellbeing, and pain relief were presented (Objective 4). Service users identified the support from navigators and service providers as a key determinant of the achieved positive outcomes.

9 Chapter 9: Quantitative results: Service user outcomes of the Luton social prescribing programme

9.1 Introduction

This chapter presents the results of the quantitative research, which addressed objective 4: To assess and explore service user outcomes of the Luton SP programme. First, the results of the descriptive analysis are presented. Then the results of the SN regression to assess the change in mental wellbeing and Bayesian approach to assess the change in energy expenditure are presented.

9.2 Objective 4: Service user outcomes

9.2.1 Descriptive analysis

In total, 448 service users were included in the available database. Three out of four navigators transparently reported that all referrals they have received were included in the database, independent from whether patients engaged in the first appointment with the navigator or not. It was not clear, due to poor reporting, whether one navigator included only those patients she had seen or all received referrals into the database. By the time I had access to the data, this navigator resigned from the programme and did not engage in any further correspondence. Therefore, it is possible that more than the 448 service users included in this analysis were referred to the programme between January 2016 and February 2018.

Socio-demographic characteristics

Socio-demographic characteristics of the 448 patients referred to the SP programme (gender, age, and working status) and the related proportions of missing data are displayed in Table 15.

Table 15: Socio-demographic characteristics of referred patients (N=448) and proportions of missing data

Characteristics	N (%)
Sex	
Female	292 (65.2)
Male	144 (32.1)
Data missing	12 (2.7)
Employment	
Working	54 (12.0)
Not working	266 (59.4)
Data missing	128 (28.6)
	Mean (SD), missing data N (%)
Age	50.3 (16.8), 14 (3.1)

Referrals

The analysis of the sources of referrals (i.e. GPs) showed that referrals to the navigators were dominated by one or two GPs instead of being equally spread across participating GPs. Out of 124 reported referrals to Navigator 1 across two general practices (the total number of involved GPs is unclear but based on the data at least 11 GPs processed referrals to Navigator 1), 70.2% were made by one GP (Table 16). Out of 181 reported referrals to Navigator 2 across two general practices (the total number of involved GPs is unclear but based on the data at least nine GPs processed referrals to Navigator 2), 58% were made by one GP (Table 16). Out of 33 reported referrals to Navigator 3 working with one practice (the total number of involved GPs is unclear but based on the data at least eight GPs processed referrals to Navigator 3), 39.4% were made by one GP and 33.4% were made by a second GP (Table 16). Navigator 4 did not report any data on the sources of referral.

Table 16: Referrals by GPs to navigator 1, 2, and 3, absolute number (N) and percentage (%)

	Navigator 1		Navigator 2		Navigator 3	
GP	N	%	N	%	N	%
GP1	87	70.3	105	58.0	13	39.4
GP2	18	14.5	39	21.5	11	33.3
GP3	5	4.0	20	11.0	2	6.1
GP4	3	2.4	6	3.3	2	6.1
GP5	3	2.4	5	2.8	2	6.1
GP6	2	1.6	2	1.1	1	3.0
G87	2	1.6	2	1.1	1	3.0
GP8	1	0.8	1	0.6	1	3.0
GP9	1	0.8	1	0.6		
GP10	1	0.8				
GP11	1	0.8				
Total	124	100	181	100	33	100

Mental wellbeing

As demonstrated in Table 17, data on mental wellbeing, collected with the SWEMWBS, at baseline and post-intervention, were incomplete for individuals referred to the programme.

Table 17: Available data on mental wellbeing pre- and post-intervention (N=448)

Mental wellbeing (SWEMWBS)	N (%)
Baseline	162 (36.2)
Data missing	286 (63.8)
Post intervention	68 (15.2)
Data missing	380 (84.8)

As pre- and post-intervention data collected with the SWEMWBS is complete for 68 individuals (Table 17), this sample (N=68) is used to provide descriptive statistics. Table 18 demonstrates the socio-demographic characteristics of this sample and the missing data.

Table 18: Socio-demographic characteristics of sample (N=68) for baseline and post-intervention data collected with the SWEMWBS and proportions of missing data

Characteristics	N (%)
Sex	
Female	45 (66.2)
Male	23 (33.8)
Data missing	0 (0.0)
Employment	
Working	22 (32.4)
Not working	41 (60.3)
Data missing	5 (7.3)
	Mean (SD), missing data N (%)
Age	49.4 (14.7), 0 (0.0)

Table 18 shows that data on the working status is missing for five individuals (7.3%). Thus, 63 individuals will be included in the final analysis (with complete pre- and post-score data and covariate information). Table 19 demonstrates the socio-demographic characteristics of the complete-case sample (N=63).

Table 19: Socio-demographic characteristics of sample (N=63) included in the final analysis of the SWEMWBS data

Characteristics	N (%)
Sex	
Female	40 (63.5)
Male	23 (36.5)
Data missing	0 (0.0)
Employment	
Working	22 (34.9)
Not working	41 (65.1)
Data missing	0 (0.0)
	Mean (SD), missing data N (%)
Age	49.6 (14.9), 0 (0.0)

In total, 63 individuals were included in the analysis (i.e. those with complete baseline, post intervention, and covariate data). Table 20 shows that the mean SWEMWBS score increased post-intervention compared to the baseline measure (2.76 point increase), indicating a possible improvement in mental wellbeing. In addition, the lowest observed score pre-intervention was seven (lowest possible mental wellbeing score), which increased to ten post-intervention. The highest observed score pre-intervention was 31, which increased to 35 (highest possible mental wellbeing score) post-intervention. This trend indicates a possible improvement in the lowest observed and highest observed mental wellbeing scores in the total study sample.

Table 20: Mean SWEMWBS scores pre and post intervention (N=63)

	Sample size (N)	Mean (SD)	Minimum score, maximum score (Range)
SWEMWBS pre intervention	63	19.73 (5.30)	7, 31 (24)
SWEMWBS post intervention	63	22.49 (5.39)	10, 35 (25)

From the histogram (Figure 10) it is clear that the difference scores do not follow a normal distribution. In line with this visual assessment, the result of the statistically powerful Shapiro-Wilk test for normality showed that the null hypothesis of a normally distributed difference score is rejected ($W(63) = 0.953$, $p=0.018$). Thus, the data do not satisfy the normality assumption of the paired t-test. The box-and-whisker plot (Figure 11) demonstrates that two mild outliers exist in the distribution of the difference score. Moreover, the box-and-whisker plot (Figure 11) shows that the distribution of the difference score is not symmetric. Thus, the data violates the assumption of the Wilcoxon signed rank test that the distribution of the difference score is symmetric (Rietveld and van Hout, 2017).

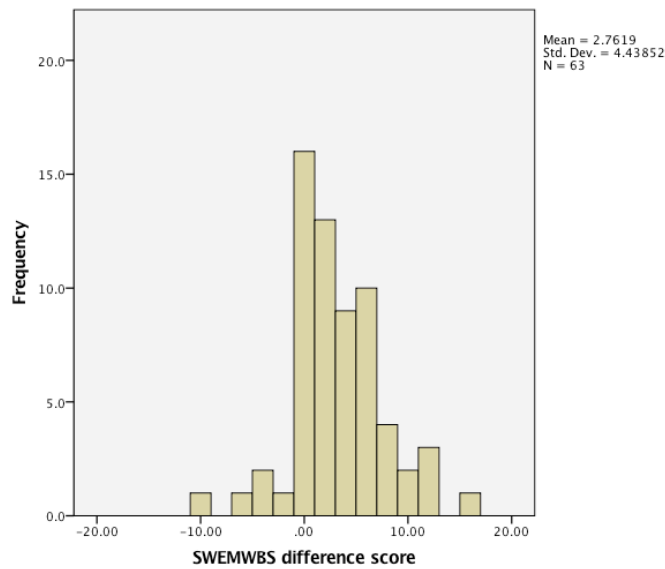


Figure 10: Histogram of the SWEMWBS difference score distribution (N=63)

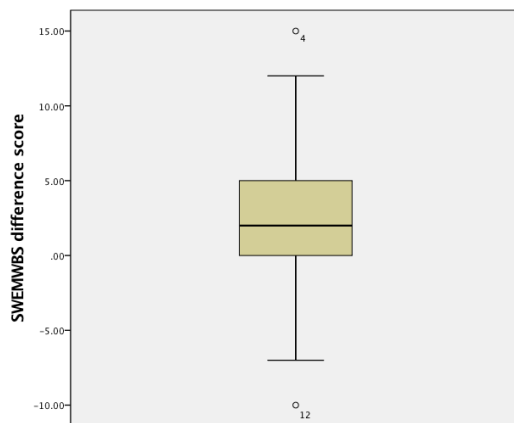


Figure 11: Box and whisker plot of the SWEMWBS difference score distribution (N=63)

Descriptive analyses found that men have a slightly lower observed mean SWEMWBS score at baseline than females (Table 21). The difference between the baseline and post-intervention observed mean SWEMWBS score is slightly higher for males than for females (Table 21). The baseline observed mean SWEMWBS score is slightly lower for those participants who are classified as not working, compared to those classified as working (Table 22). The observed mean difference is almost twice as much in those classified as not working, compared to those classified as working. The age variable was divided into 10-year intervals for clarity of descriptive statistics. At baseline, the age group 44-53 years had the lowest observed mean SWEMWBS score, and the age group 54-63 years the highest observed mean score (Table 23). The biggest sample mean difference in SWEMWBS scores was observed in the age group 64-73 years, and the smallest in the age group 34-43 years (Table 23).

Table 21: Baseline and post-intervention mean SWEMWBS scores by sex

Sex	Sample size (N)	Baseline SWEMWBS mean (SD)	Post-intervention SWEMWBS mean (SD)	Mean difference in SWEMWBS score (SD)
Male	23	19.44 (6.27)	22.87 (5.00)	3.43 (4.62)
Female	40	19.90 (4.74)	22.28 (5.65)	2.38 (4.34)

Table 22: Baseline and post-intervention mean SWEMWBS scores by working status

Employment status	Sample size (N)	Baseline SWEMWBS mean (SD)	Post-intervention SWEMWBS mean (SD)	Mean difference in SWEMWBS score (SD)
Working	22	20.86 (4.35)	22.63 (6.01)	1.77 (4.69)
Not working	41	19.12 (4.62)	22.42 (5.10)	3.30 (4.26)

Table 23: Baseline and post-intervention mean SWEMWBS scores by age

Age (10-year intervals)	Sample size (N)	Baseline SWEMWBS mean (SD)	Post-intervention SWEMWBS mean (SD)	Mean difference in SWEMWBS score (SD)
24-33	12	18.64 (3.67)	20.18 (4.67)	1.58 (3.48)
34-43	10	18.90 (6.44)	19.70 (5.50)	0.80 (3.19)
44-53	16	18.13 (6.43)	22.19 (4.64)	4.06 (5.66)
54-63	13	22.77 (4.62)	25.00 (5.37)	2.23 (3.06)
64-73	8	20.38 (3.38)	26.38 (5.04)	6.00 (5.58)
74-83	4	20.25 (5.62)	21.50 (6.25)	1.25 (1.50)

Energy expenditure

The distributions of all outcome variables (Walking MET, Moderate MET, Vigorous MET, and Total MET minutes/week pre- and post-intervention) were positively skewed. The difference scores (D) for Walking MET, Moderate MET, Vigorous MET, and Total MET minutes/week, were non-normally distributed, non-symmetric, and include outliers (Appendix 23). As demonstrated in Table 24, data on energy expenditure, collected with the IPAQ-SF, at baseline and post-intervention, were incomplete for individuals referred to the programme.

Table 24: Available data on energy expenditure pre- and post-intervention (N=448)

MET minutes per week (IPAQ-SF)	N (%)
Baseline	186 (41.5)
Data missing	262 (58.5)
Post intervention	56 (12.5)
Data missing	392 (87.5)

Out of the 186 individuals for whom baseline data were collected, 56 (30.1%) scored a zero for each IPAQ-SF question, indicating that they have not done any walking, moderate, or vigorous physical activity in the previous seven days. Six (3.2%) out of the 186 individuals reported vigorous physical activity over the previous seven days at baseline. The majority of the 186 individuals (N=118, 63.4%) engaged in walking, and 38 individuals (20.4%) in moderate physical activity at baseline. Individuals could engage in walking, moderate, and vigorous physical activity in the previous seven days, therefore each individual can be counted in more than one physical activity category.

As 58.5% (N=262) of baseline data collected with the IPAQ-SF is missing (Table 24), the 41.5% (N=186) of the original sample (N=448) is used to provide descriptive statistics for complete data of energy expenditure at baseline. Table 25 provides an overview of the characteristics of service users from whom baseline data was collected.

Table 25: Socio-demographic characteristics of sample (N=186) for baseline data collected with the IPAQ-SF and proportions of missing data

Characteristics	N (%)
Sex	
Female	131 (70.4)
Male	55 (29.6)
Data missing	0 (0.0)
Employment	
Working	32 (17.2)
Not working	115 (61.8)
Data missing	39 (21.0)
	Mean (SD), missing data N (%)
Age	51.2 (15.7), 1 (0.5)

As shown in Table 25, 21% (N=39) of data on the working status and 0.5% (N=1) of data on age are missing for individuals with baseline data on their physical activity. For additional analysis methods, individuals with complete covariate and baseline information only are included in the final analysis of energy expenditure. Table 26 presents the characteristics of the complete-case sample (N=146) included in the final analysis of energy expenditure.

Table 26: Socio-demographic characteristics of sample (N=146) included in the final analysis of IPAQ-SF data (i.e., with complete covariate and baseline data)

Characteristics	N (%)
Sex	
Female	102 (69.9)
Male	44 (30.1)
Data missing	0 (0.0)
Employment	
Working	32 (21.9)
Not working	114 (78.1)
Data missing	0 (0.0)
	Mean (SD), missing data N (%)
Age	51.3 (15.8), 0 (0)

9.2.2 Mental wellbeing: Skew-Normal regression

In total, 63 individuals were included in the final analysis of mental wellbeing. The socio-demographic characteristics of the study sample are outlined in Table 19. The results of the SN regression showed a statistically significant change ($P < 0.001$) in the average difference score between baseline and post-intervention measures (Table 27). The SWEMWBS score increased from baseline to post-intervention measures by an average of 2.78 points (95% CI 1.68, 3.88) within the sample.

Table 27: SN regression model results (N=63)

Variables	Regression coefficient	Standard errors	P-value (95% CI)
Intercept	2.78	0.55	$P < 0.001$ (1.68, 3.88)

Clinical relevance

As shown in Table 27, the observed mean points difference in SWEMWBS scores is 2.78 (95% CI 1.68, 3.88) between baseline and post-intervention measures. As previously discussed in Chapter 6, section 6.4.4, a change of three or more units in SWEMWBS scores could be interpreted as a clinically significant change (Maheswaran *et al.*, 2012; Putz. R., O'Hara, K., Taggart, F. and Stewart-Brown, 2012). Thus, although a statistically significant increase (indicating improvement) was observed in the mean SWEMWBS score post-intervention, compared to baseline, it is unlikely that the observed mean change of 2.78 in the study sample was clinically meaningful.

9.2.3 Energy expenditure: Bayesian zero-inflated negative binomial model

In total, 146 individuals containing complete covariate information at baseline were included in the final analysis of energy expenditure. The socio-demographic characteristics of the

study sample are outlined in Table 26. Throughout this whole results section, Walking MET minutes/week are referred to as Walking MET, Moderate MET minutes/week as Moderate MET, Vigorous MET minutes/week as Vigorous MET, and Total MET minutes/week as Total MET.

Walking MET minutes per week

The expected increase in the mean non-zero Walking MET score due to the intervention is approximately 41.7% (95% PPI 40.31%, 43.11%) and the change is clearly positive. Therefore, an increase of 41.7% in the Walking MET score is expected for individuals with a non-zero walking MET score at baseline. The average increase in the probability of observing non-zero Walking MET scores due to the intervention is 25.2% (95% PPI 11.66%, 37.37%) and the change is clearly positive. In other words, the average decrease in the probability of observing a zero Walking MET score post-intervention is 25%. It is important to note that unlike the common percent increase in mean non-zero Walking MET scores, the percent increase and decrease of the probability of observing non-zero MET scores resulting from the intervention is individual specific. What is reported here is the increase/decrease in average probability of observing non-zero scores resulting from the intervention across the sample. The increases and decreases in the probability of observing non-zero MET scores are based on the pre-intervention probability of individuals. It is the pre-intervention probability that defines how much the probability increases/decreases due to the intervention, taking the nature of probabilities (bounded between 0 and 1) into account. For example, if an individual in the sample has a pre-intervention probability of observing a non-zero score equal to 80%, we cannot expect an increase of 25% (the average increase based on the sample) for this individual, because that would be 105%.

Effect of age, gender, and working on the mean non-zero Walking MET score and corresponding probabilities of observing non-zero Walking MET scores

Based on the coding of variables, the gender component is the incremental effect of being male on the mean non-zero MET score and corresponding probabilities of non-zero MET scores. The working component is the incremental effect of working on the mean non-zero MET score and corresponding probabilities of non-zero MET scores.

There seems to be a strong negative effect of age on the mean non-zero Walking MET score ($\beta_1 = -0.006$, 95% PPI -0.0067, -0.0059). This indicates that the older the individual the lower the expected Walking MET score. Similarly, there is strong evidence for a positive effect of gender on the mean non-zero Walking MET score ($\beta_2 = 0.38$, 95% PPI 0.37, 0.39). Thus,

males have a higher expected non-zero Walking MET score than females. Lastly, there is a strong negative effect of work on the mean non-zero Walking MET score ($\beta_3 = -0.11$ 95% PPI -0.12, -0.097). This indicates that those individuals who are working have a lower expected non-zero Walking MET score than those who are not working.

There is unclear evidence on the effect of age on the probability of observing a non-zero Walking MET score, as the posterior distribution spreads across the negative and positive territory ($\beta_1^* = -0.01$, 95% PPI -0.032, 0.0091). However, as most of the posterior distribution is in the negative territory, it is likely that there is a negative effect of age on the probability, indicating that the higher the age of an individual, the lower the probability of a non-zero Walking MET score. The effect of gender on the probability of observing a non-zero Walking MET score is unclear. While the mean probability is slightly positive ($\beta_2^* = 0.1$), almost half of the posterior distribution is in the negative territory (95% PPI -0.54, 0.84). Therefore, there is no indication of an impact of gender on the probability of observing a non-zero Walking MET score. Lastly, the effect of working on observing non-zero Walking MET scores is unclear ($\beta_3^* = -0.75$, 95% PPI -1.60, 0.058). A summary of results is displayed in Table 28.

Table 28: Summary of results for Walking MET scores

Outcomes	Mean (%) (95% Posterior Probability Interval)
Common percent (%) increase in mean non-zero Walking MET score	Strong evidence for positive effect 41.7 (40.31, 43.11)
Average increase in the probability of observing non-zero Walking MET scores	Strong evidence for positive effect 25.2 (11.66, 37.37)
Effects of covariates	Direction and strength of evidence Mean Effect (95% Posterior Probability Interval)
Effect of age on the mean non-zero Walking MET score	Strong evidence for negative effect -0.006 (-0.0067, -0.0059)
Effect of age on the probability of observing non-zero Walking MET scores	Unclear evidence for effect -0.01 (-0.032, 0.0091)
Effect of gender* on the mean non-zero Walking MET score	Strong evidence for positive effect 0.38 (0.37, 0.39)
Effect of gender* on the probability of observing non-zero Walking MET scores	Unclear evidence for effect 0.15 (-0.54, 0.84)
Effect of working status** on the mean non-zero Walking MET score	Strong evidence for negative effect -0.11 (-0.12, -0.097)
Effect of working status** on the probability of observing non-zero Walking MET scores	Unclear evidence for effect -0.75 (-1.60, 0.058)

*The gender component is the incremental effect of being male on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

**The working status component is the incremental effect of working on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

Moderate MET minutes per week

The expected increase in the mean non-zero Moderate MET score due to the intervention is 5.0% (95% PPI 2.94%, 7.09%) and the change is clearly positive. Therefore, an increase of 5% in the Moderate MET score is expected for individuals with a non-zero score at baseline. The average increase in the probability of observing non-zero Moderate MET scores due to the intervention is 23.5% (95% PPI 9.05%, 38.08%) and the change is clearly positive. In other words, the average decrease in the probability of observing zero Moderate MET scores post-intervention is 23.5%.

Effect of age, gender, and working on the mean non-zero Moderate MET score and corresponding probabilities of observing non-zero Moderate MET scores

There is strong evidence for a negative effect of age on the mean non-zero Moderate MET score ($\beta_1 = -0.01$, 95% PPI -0.011, -0.0089). Hence, the older an individual, the lower the expected non-zero Moderate MET score. The negative effect of gender on the mean non-zero Moderate MET score appears to be strong ($\beta_2 = -0.45$, 95% PPI -0.48, -0.42). This indicates that males have a lower expected non-zero Moderate MET score than females. There is no clear indication of an impact of working on the mean non-zero Moderate MET score. As the mean is slightly positive (0.03), and the majority of the posterior distribution is in the positive territory (95% PPI -0.00014, 0.053), it is likely that those who are working have a higher expected non-zero Moderate MET score than those who are not working. However, there is unclear evidence for this association.

There is strong evidence for a negative effect of age on the probability of observing non-zero Moderate MET scores ($\beta_1^* = -0.03$, 95% PPI -0.057%, -0.012%). This indicates that the higher the age of an individual, the lower the probability of observing non-zero Moderate MET scores. The effect of gender on the probability is unclear ($\beta_2^* = 0.07$). As the posterior distribution is almost equally spread across the negative and positive territory (95% PPI -0.65%, 0.78%), there is no existing evidence for the impact of gender on the probability of observing non-zero Moderate MET scores. Lastly, there is unclear evidence on the effect of working on the probability of observing non-zero scores. However, as the mean is positive ($\beta_2^* = 0.05$) and most of the posterior distribution is in the positive territory (95% PPI -0.27%, 1.34%), it is likely that there is a positive effect of working on the probability of observing non-zero Moderate MET scores (i.e. working individuals likely have a higher probability of non-zero Moderate MET scores compared to not working individuals). A summary of results is displayed in Table 29.

Table 29: Summary of results for Moderate MET scores

Outcomes	Mean (%) (95% Posterior Probability Interval)
Common percent (%) increase in mean non-zero Moderate MET score	Strong evidence for positive effect 5.0 (2.94, 7.09)
Average increase in the probability of observing non-zero Moderate MET scores	Strong evidence for positive effect 23.5 (9.05, 38.08)
Effects of covariates	Direction and strength of evidence Mean Effect (95% Posterior Probability Interval)
Effect of age on the mean non-zero Moderate MET score	Strong evidence for negative effect -0.01 (-0.011, -0.0089)
Effect of age on the probability of observing non-zero Moderate MET scores	Strong evidence for negative effect -0.03 (-0.057, -0.012)
Effect of gender* on the mean non-zero Moderate MET score	Strong evidence for negative effect -0.45 (-0.48, -0.42)
Effect of gender* on the probability of observing non-zero Moderate MET scores	Unclear evidence for effect 0.07 (-0.65, 0.78)
Effect of working status** on the mean non-zero Moderate MET score	Unclear evidence for effect 0.03 (-0.00014, 0.053)
Effect of working status** on the probability of observing non-zero Moderate MET scores	Unclear evidence for effect 0.52 (-0.27, 1.34)

*The gender component is the incremental effect of being male on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

**The working status component is the incremental effect of working on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

Vigorous MET-minutes per week

The expected increase in the mean non-zero Vigorous MET score due to the intervention is 107.3% (95% PPI 98.19%, 116.20%) and the change is clearly positive. Therefore, an increase of 107.3% in the Vigorous MET score is expected for individuals with a non-zero Vigorous MET score at baseline. The average increase in the probability of observing non-zero Vigorous MET scores due to the intervention is 6.0% (95% PPI -1.21%, 15.07%), but since the 95% PPI for the probability of observing non-zero MET scores post-intervention contains a negative and positive value, the evidence is unclear.

Effect of age, gender, and working on the mean non-zero Vigorous MET score and corresponding probabilities of observing non-zero Vigorous MET scores

There is strong evidence for a negative effect of age on the mean non-zero Vigorous MET scores ($\beta_1 = -0.006$, 95% PPI -0.0075%, -0.0036%). This negative effect indicates that the older an individual, the lower the expected non-zero Vigorous MET score. The negative effect of gender on the mean non-zero Vigorous MET scores appears to be strong, too ($\beta_2 = -0.3$, 95% PPI -0.30%, -0.21%). Being male has an association with lower expected Vigorous

MET scores than being female. Lastly, there is strong evidence for a negative effect of working on the mean non-zero Vigorous MET scores ($\beta_3=-0.4$, 95% PPI -0.43, -0.34), indicating that those who are working have a lower expected non-zero Vigorous MET score than those who are not working.

There is unclear evidence for the effect of age on the probability of observing non-zero Vigorous MET scores. However, as the mean is negative ($\beta_1^*=-0.03$), and most of the posterior distribution is in the negative territory (95% PPI -0.74, 0.019), it is likely that the older an individual, the lower the probability of observing non-zero Vigorous MET scores. The effect of gender on the probability of observing non-zero scores is unclear. While the mean is positive ($\beta_2^*=0.2$), almost half of the posterior distribution is in negative territory (95% PPI -1.16, 1.50), indicating that there is no evidence for an effect of gender on the probability of observing non-zero Vigorous MET scores. Lastly, there is unclear evidence for the effect of working on the probabilities of observing non-zero Vigorous MET scores. However, as the mean is negative ($\beta_3^*=-1.0$), and most of the posterior distribution is in the negative territory (95% PPI -2.35, 0.25), it is likely that working has a negative effect on the probability of observing non-zero Vigorous MET scores. Hence, it is likely that working individuals have a lower probability of non-zero Vigorous MET scores than not working individuals. A summary of results is displayed in Table 30.

Table 30: Summary of results for Vigorous MET scores

Outcomes	Mean (%) (95% Posterior Probability Interval)
Common percent (%) increase in mean non-zero Vigorous MET score	Strong evidence for positive effect 107.3 (98.19, 116.20)
Average increase in the probability of observing non-zero Vigorous MET scores	Unclear evidence for effect 6.0 (-1.21, 15.07)
Effects of covariates	Direction and strength of evidence Mean Effect (95% Posterior Probability Interval)
Effect of age on the mean non-zero Vigorous MET score	Strong evidence for negative effect -0.006 (-0.0075, -0.0036)
Effect of age on the probability of observing non-zero Vigorous MET scores	Unclear evidence for effect -0.03, (-0.74, 0.019)
Effect of gender* on the mean non-zero Vigorous MET score	Strong evidence for negative effect -0.26 (-0.30, -0.21)
Effect of gender* on the probability of observing non-zero Vigorous MET scores	Unclear evidence for effect 0.19 (-1.16, 1.50)
Effect of working status** on the mean non-zero Vigorous MET score	Strong evidence for negative effect -0.38 (-0.43, -0.34)
Effect of working status** on the probability of observing non-zero Vigorous MET scores	Unclear evidence for effect -1.0 (-2.35, 0.25)

*The gender component is the incremental effect of being male on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

**The working status component is the incremental effect of working on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

Total MET minutes per week

The expected increase in the mean non-zero Total MET score due to the intervention is 56.3% (95% PPI 54.77%, 57.69%) and the change is clearly positive. Therefore, an increase of 56.3% in the Total MET score is expected for individuals with a non-zero Total MET score at baseline. The average increase in the probability of observing a non-zero Total MET score due to the intervention is 26.4% (95% PPI 14.98%, 36.40%) and the change is clearly positive. In other words, the average decrease in the probability of observing a zero Total MET score post-intervention is 26.4%.

Effect of age, gender, and working on the mean non-zero Total MET score and corresponding probabilities of observing non-zero Total MET scores

There is strong evidence for a negative effect of age on the mean non-zero Total MET score ($\beta_1 = -0.01$, 95% PPI -0.012, -0.011), indicating that the older an individual, the lower the expected mean non-zero Total MET score. There is a strong positive effect of gender on the mean non-zero Total MET score ($\beta_2 = 0.09$, 95% PPI 0.080, 0.10), indicating that men have a higher expected mean non-zero Total MET score than women. Lastly, there is a strong

negative effect of working on the mean non-zero Total MET score ($\beta_3=-0.08$, 95% PPI -0.087, -0.067). This indicates that working individuals have a lower expected non-zero Total MET mean score than not working individuals.

While the mean for the effect of age on the probability of observing a non-zero Total MET score is slightly negative ($\beta_1^*=-0.01$), a good portion of the posterior distribution is in the positive territory (95% PPI -0.035, 0.0097). Therefore, the effect is unclear and there is no indication of an impact of age on the probability of observing non-zero Total MET scores. For the effect of gender, the mean is positive ($\beta_2^*=0.7$) and most of the posterior distribution is in the positive territory (95% PPI -0.039, 1.56), indicating that it is likely that men have a higher probability of non-zero Total MET scores than women. However, the evidence for this effect remains unclear. Lastly, for the effect of working, the mean is negative ($\beta_3^*=-0.8$) and most of the posterior distribution is in the negative territory (95% PPI -1.81, 0.087). Therefore, while the existing evidence is unclear, it is likely that working individuals have a lower probability of non-zero Total MET scores than not working ones. A summary of results is displayed in Table 31.

Table 31: Summary of results for Total MET scores

Outcomes	Mean (%) (95% Posterior Probability Interval)
Common percent (%) increase in mean non-zero Total MET score	Strong evidence for positive effect 56.3 (54.77, 57.69)
Average increase in the probability of observing non-zero Total MET scores	Strong evidence for positive effect 26.4 (14.98, 36.40)
Effects of covariates	Direction and strength of evidence Mean Effect (95% Posterior Probability Interval)
Effect of age on the mean non-zero Total MET score	Strong evidence for negative effect -0.01 (-0.012, -0.011)
Effect of age on the probability of observing non-zero Total MET scores	Unclear evidence for effect -0.01 (-0.035, 0.0097)
Effect of gender* on the mean non-zero Total MET score	Strong evidence for positive effect 0.09 (0.080, 0.10)
Effect of gender* on the probability of observing non-zero Total MET scores	Unclear evidence for effect 0.74 (-0.039, 1.56)
Effect of working status** on the mean non-zero Total MET score	Strong evidence for negative effect -0.08, (-0.087, -0.067)
Effect of working status** on the probability of observing non-zero Total MET scores	Unclear evidence for effect -0.82, (-1.81, 0.087)

*The gender component is the incremental effect of being male on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

**The working status component is the incremental effect of working on the mean non-zero MET scores and corresponding probabilities of non-zero MET scores

9.2.4 Summary of results

The SN regression found a statistically significant increase in SWEMWBS scores (measuring mental wellbeing) post-intervention, compared to the baseline measures. However, it is unlikely that the observed change in the Luton cohort is clinically relevant. The descriptive analysis has revealed that the difference in observed mean SWEMWBS scores post-intervention is slightly higher for males than for females. The observed mean difference post-intervention is almost twice as much in those classified as not working, compared to those classified as working. Lastly, the descriptive analysis found that the change in mean SWEMWBS scores post-intervention was the lowest in the age group 44-53 years and the highest in the age group 64-73 years.

Using a Bayesian zero-inflated negative binomial model to account for a large number of observed zeros in the data, 95% posterior intervals showed that mean energy expenditure from all levels of physical activities increased post-intervention (walking 41.7% (40.31%, 43.11%); moderate 5.0% (2.94%, 7.09%); vigorous 107.3% (98.19%, 116.20%); and total

56.3% (54.77%, 57.69%)). The probability of observing energy expenditure, and therefore physical activity, post-intervention increased in total and for two (walking, moderate) of three MET physical activity levels, for those individuals who were inactive at the start of the programme. These results indicated that the Luton SP programme has the potential to engage inactive patient groups in physical activities. In addition, the study found that age has a negative effect on energy expenditure from any physical activity level (i.e., older individuals have lower expected MET scores). Similarly, working status has a negative effect on energy expenditure in all but one MET physical activity level (i.e., working individuals have lower expected MET scores). No consistent pattern was observed across physical activity levels in the association between gender and energy expenditure (i.e., males have higher expected Walking and Total MET scores, whereas females have higher Moderate and Vigorous MET scores).

9.3 Chapter summary

This chapter has presented the results of the statistical analysis of secondary data, which aimed to assess the change in mental wellbeing and energy expenditure between the baseline and post-intervention measures. The descriptive analysis assessed the relationships between the covariates age, sex, and working status and mental wellbeing. The study also found a statically significant increase in the mean SWEMWBS score post-intervention, however, it is unlikely that the observed increase in mental wellbeing is clinically relevant. There is evidence for increased levels of energy expenditure post-intervention, and the potential of the Luton SP programme to engage inactive patient groups in physical activity. In addition, the associations between the covariates age, sex, and working status and energy expenditure were assessed.

10 Chapter 10: Discussion

10.1 Introduction

Chapter 7 to Chapter 9 have presented the findings and results of this study. This chapter turns its attention to a discussion of the findings and results in the context of the existing evidence on SP and similar integrated care initiatives. Additionally, it highlights how the findings of this study relate to the RMIC, which provides the theoretical underpinning for this study (Chapter 4). This chapter concludes with a discussion of the study limitations.

10.2 Discussion of objective 1

Objective 1 aimed to collect and synthesise evidence on (i) factors that facilitate and hinder the implementation of SP programmes in the UK, and (ii) the impact of SP on service users. A systematic review of the literature was conducted, including searches of eleven databases, the grey literature, and reference lists of relevant papers. The findings were synthesised narratively.

This study was the first to systematically collect and synthesise the evidence on facilitators and barriers to implementation and service user outcomes of SP. Thus, this review addressed the identified gaps in the literature and evidence base for SP. Many previous studies focused on patient outcomes specifically, however, none of the included studies in the review focused on barriers and enablers to implementation. This finding is similar to the finding of recent scoping review, on the implementation of patient navigation programmes linking primary care with community-based health and social services, that none of the included papers focused on the implementation of navigation programs specifically (Valaitis *et al.*, 2017). Out of the 19 evaluations that met the inclusion criteria of this review, twelve were written as descriptive reports with limited information on the methodology of the studies, and seven were published in academic journals. Four of the included published papers were published in 2017, indicating a recent increase in the dissemination of findings on SP in academic journals. Using the MMAT-V 2011 (Pluye *et al.*, 2011) to appraise the quality of included studies, most studies attained a low quality score (see Table 9) due the lack of clear objectives, and poor reporting of sampling, data collection, and analysis methods. In addition, included quantitative studies were limited by sparse data on numbers of participants, attendance of services, and high loss of follow-up, small study samples, the lack of control groups, and validated measurement tools. The low quality scores may partly be explained by the fact that most existing evaluation reports were not published and therefore did not adhere to formal reporting standards expected in academic journal articles and assessed with the MMAT-V 2011. Limited resources, practical barriers, and the lack of expertise may have hindered the robust evaluation of local SP programmes (Woodall *et al.*, 2018).

10.2.1 Primary outcome: Facilitators and barriers to the implementation of social prescribing in the UK

Following narrative analysis, eight themes were identified: Operational processes, Navigator-ready surgeries, shared knowledge and understanding, communication and relationships, human resources, referral process, patient uptake and adherence, and third sector resources.

It became apparent that most factors were identified as facilitators, if present, and barriers if absent (e.g. shared understanding vs. the lack of shared understanding, good communication vs. poor communication) in included studies. This finding is consistent with previous studies, which explored facilitators and barriers to the implementation of integrated social and healthcare programmes (RAND Europe, 2012; Mackie and Darvill, 2016; Valaitis *et al.*, 2017). Thus, it is likely that there are a set of factors that influence the implementation of SP and can turn into facilitators and barriers, rather than fixed barriers and facilitators to implementation. This finding informed the presentation of the findings by theme for facilitators and barriers together, instead of separately.

The narrative analysis revealed that the identified themes are interrelated. Thus, in addition to the expected influence of contextual factors on the implementation process (based on the critical realist stance), this study found that complex interrelationships exist between the identified facilitators and barriers to implementation (Figure 12). Findings showed that the lack of service level agreements (operational processes), for example, can contribute to the lack of shared knowledge and clarity of roles, which can result in tensions between partners, poor communication, difficulties in building new relationships, and eventually frustration and low motivation of providers. Each of the identified barriers can then trigger other barriers. This study, for example, found a bidirectional relationship between communication and relationships between partners. Eventually, poor communication was found to hinder effective partnership working, which is recognised as a key element of SP programmes. On the other hand, a phased implementation approach affected factors that were identified as facilitators in this study, namely shared understanding, good relationships between partners, and navigator ready surgeries. The demonstrated complex chain reaction between identified barriers and facilitators (see Figure 12), together with the influence of contextual factors, makes it challenging for managers and providers to predict and control the implementation process of SP programmes.

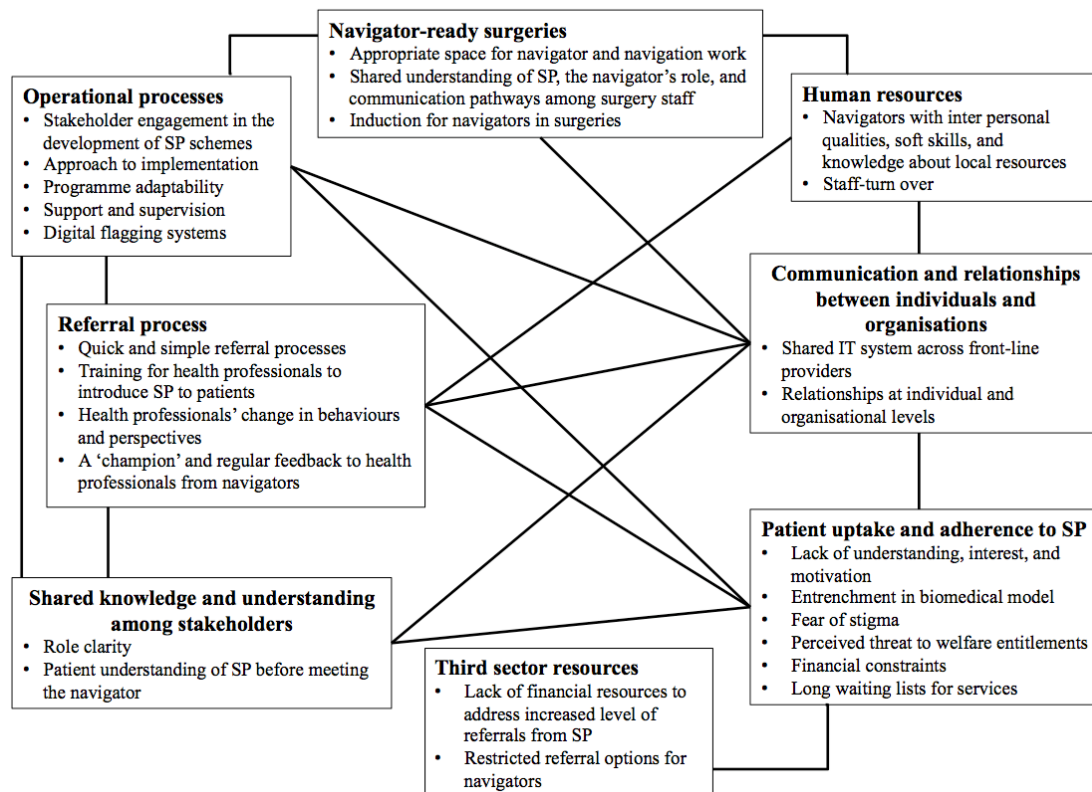


Figure 12: The interrelationship between identified factors influencing the implementation of SP programmes (Objective 1)

Most of the included studies in the review have discussed the factors influencing the implementation of SP without a theoretical framework underpinning the study. However, it becomes apparent that the findings (see Figure 12) are relevant to the multiple domains of the RMIC, providing the theoretical underpinning of this study (for a detailed description of the RMIC see Chapter 4). Effective communication and good relationships between individuals and organisations were found to be important for professional integration. Getting surgeries navigator-ready is important to achieve organisational integration. In addition, the understanding of SP at a patient level is determined by clinical integration. In addition, Navigator-ready surgeries and the referral process, for example, require *system integration* (i.e. the alignment of physical space, rules, processes, structures, and policies between integrated systems), *organisational integration* (i.e. the linked up delivery of services across sectors), *professional integration* (i.e. working relationships between partners within and across organisations), and *clinical integration* (i.e. patient care services are coordinated across various professional, institutional, and sectorial boundaries in a system). Given that identified factors such as 'Navigator-Ready surgeries' require multiple levels of integration outlined in the RMIC, further highlights the complex interrelationship of factors influencing the implementation and delivery of SP. Moreover, shared understanding and effective

communication and relationships between individuals and organisations were identified as facilitators to implementation in this study, and can fall under *normative integration* (i.e. the development and maintenance of a common frame of reference between organisations, professional groups, and individuals). In the RMIC, normative integration impacts on the integration at all levels (Valentijn *et al.*, 2013; Valentijn, Biermann and Bruijnzeels, 2016). Similarly to the theoretical assumption in the RMIC, this study found that shared understanding and the communication and relationships between individuals and organisations are key for system, organisational, professional, and clinical integration. Most included studies focused on the relationship between individuals within and across organisations. However, in line with the theoretical assumption of the RMIC, one study (Skivington *et al.*, 2018) highlighted the importance of organisational integration, beyond individual relationships, to achieve a sustainable SP service. Operational processes, such as the implementation process, supervision, and steering group oversight, fall under *functional integration* (i.e. the coordination of key support functions and activities, such as financial and information management, strategic planning and support systems). Similar to the theoretical assumption, this study found that functional integration impacted on system, organisational, professional, and clinical integration. Lastly, in line with the MRC guidelines (Moore *et al.*, 2014) and the revised RMIC, this study found that contextual factors, for example the availability of third sector resources, influence the implementation and delivery of SP, and therefore need to be considered at the planning phase of SP programmes. Overall, the findings of the review are in line with the theoretical assumptions of the RMIC that *system, organisational, professional, clinical, functional, and normative integration* underpin the implementation and operation of SP programmes.

Similarly to the findings of this study, previous research identified shared knowledge and understanding, relationships and communication, training for providers, staff turnover, early stakeholder engagement, changes in health professionals ways of working and perspectives, supervision and steering group oversight, technical resources, programme adaptability, and the role of navigators, as key factors influencing the implementation of integrated social and healthcare programmes in the UK and internationally (RAND Europe, 2012; Mackie and Darvill, 2016; Kelleher *et al.*, 2017; Valaitis *et al.*, 2017; Baxter *et al.*, 2018). Thus, the findings of this review can provide general guidance for policy-makers and providers planning to implement an integrated social and healthcare programme across different geographical settings. However, this review identified some factors specifically relevant for the implementation of SP programmes based in primary care and involving navigators, which were not discussed in the general integrated care literature. This review identified the following factors specific to a SP holistic model based in primary care: Implementation

approaches (Phased roll out vs. go live approach), Navigator-ready surgeries, practice manager's support in the development and implementation of SP in surgeries, availability of- and financial support for- third sector resources, and reasons for the programme's (non-) uptake and buy in by end users. Thus, findings of this review contribute to the evidence base on factors influencing the implementation of SP holistic models based in primary care, and can provide important insights for policy-makers and providers to overcome specific barriers. However, as the findings and theoretical underpinning of this study demonstrate, the implementation process cannot be predicted and fully controlled 'from the outside', due to the interrelationships of factors and differences between implementation settings.

10.2.2 Secondary outcome: The impact of social prescribing on service users

The aims of SP holistic programmes and their respective delivery models can have major variance. Thus, it can be challenging to synthesise, compare, and pool the wide range of quantitatively measured patient outcomes of SP programmes (Woodall *et al.*, 2018). Table 33 in Appendix 2 presents the range of different quantitative measurement tools used in included studies to assess patient outcomes. In addition, the study designs and methods of quantitative data analysis in included studies varied; some conducted hypothesis testing whereas others described quantitative patterns in the data descriptively. Given the heterogeneity and insufficient data, a meta-analysis of patient outcomes could not be conducted in this study.

The systematic review found that the results of quantitative studies assessing the change in patients' mental and physical health and wellbeing after the SP intervention were mixed. Table 33 shows that the quantitative evidence base is providing a mixed picture. In contrast to this mixed quantitative evidence base, most qualitative studies consistently found that patients experienced improvements in their health and wellbeing due to SP interventions. The observed discrepancy in results of quantitative and qualitative studies became also apparent for health-related behaviours, social interactions, and activities of daily living; quantitative results were mixed whereas qualitative studies consistently reported positive outcomes. These findings are consistent with previous mixed methods evaluations of SP, which identified that the quantitative data did not support or reflect the positive findings of the qualitative studies (The Health Foundation, 2015; Carnes *et al.*, 2017). Disagreement between qualitative and quantitative findings is particularly problematic when studies are used to inform policy and practice (Slonim-Nevo and Nevo, 2009). Decision-makers are faced with the challenge to decide which findings to use, those obtained from qualitative methods such as interviews or those obtained from quantitative methods using standardised scales (Slonim-Nevo and Nevo, 2009). However, the observed discrepancy between the qualitative and quantitative literature on SP raised the following question among researchers; 'Why are the findings coming from

qualitative methods conflict with those arriving from quantitative methods?’ (Carnes *et al.*, 2017)

The observed inter-method discrepancy could be justified by potential methodological limitations and problems in qualitative or quantitative studies (Slonim-Nevo and Nevo, 2009). A common limitation of included quantitative studies was a small sample size, and thus included studies may not be powered to detect small differences in all outcome measures (Moffatt *et al.*, 2006). None of the included studies reported sample size calculations. Therefore the power of included studies remains unknown. In contrast to quantitative studies, qualitative studies provide us with the participants’ personal stories, subjective feelings, and thoughts. Quantitative tools to measure patient outcomes were criticised for not being able to explore the internal, subjective, and complex world of individuals (Slonim-Nevo and Nevo, 2009). It could be that the standardised health outcome measures are not able to capture patients’ priorities, experiences, and perspectives as it is possible with qualitative data collection methods, which may partly explain the observed discrepancy in findings (Carnes *et al.*, 2017). Another point worth making is that navigators were responsible for selecting service users for the qualitative outcome evaluations in most included studies. If service users were randomly selected for interviews, response rates were very low (e.g. 5%) (The Health Foundation, 2015; Carnes *et al.*, 2017). As navigators may have an interest in a positive presentation of the programme they are working in, it is possible that they have mainly selected service users with positive experience and outcomes for the evaluations. Thus, selection bias could explain the observed positive trend in qualitative findings (Moffatt *et al.*, 2006). Moreover, public health interventions, such as SP, that require active participation, engagement, and commitment to improve a person’s health and wellbeing might be ‘dose’ dependent (Carnes *et al.*, 2017). Some outcomes may also require more exposure and attendance to SP than others, but little is known about the relationships between the levels of service user exposure and outcomes of SP (Barte and Wendel-Vos, 2017). Most of the included studies did not report participants’ attendance at navigator appointments and to referred activities (i.e. adherence). However, it is possible that negative quantitative results can be attributed to non-adherence of individuals in the study sample, rather than an unsuccessful intervention. Thus, divergent findings may also be explained by differences in adherence levels and experiences of participants in qualitative and quantitative samples (Moffatt *et al.*, 2006). Critical realists do not commit to a single type of research methods, instead they accept that qualitative and quantitative research methods have complementary strengths and limitations (Sayer, 2000). Thus, from a critical realist perspective it would be a fault to dismiss or question either qualitative or quantitative results at this stage. More robust and transparent mixed methods research is needed on patient outcomes of SP to investigate

and understand discrepancies in findings. In contrast to this review, previous reviews on the evidence of SP outcomes for patients in the UK and internationally did not report a discrepancy in results of qualitative and quantitative studies (Bickerdike *et al.*, 2017; Valaitis *et al.*, 2017). Thus, this finding contributes to the growing knowledge on service user outcomes and outcome evaluations of SP services.

With one exception for self-confidence (where an unspecified quantitative scale was used to assess changes in self-confidence before and after a SP programme), qualitative studies only reported changes in self-concepts, feelings, and skills after SP programmes. This may be related to a previously discussed point; that in contrast to quantitative standardised measurement tools, qualitative methods enable the exploration of subjective thoughts and feelings, as well as the patient priorities and outcomes from their perspective. The outcomes from the patient perspective may also be unanticipated outcomes for researchers, practitioners, and policy-makers. These outcomes would remain unknown if outcome evaluations would be based on quantitative analysis only (Moore *et al.*, 2014; Loftus, McCauley and McCarron, 2017). Thus, in line with a critical realist view, the inclusion of qualitative and quantitative evidence enabled a level of analysis and interpretation that would not be possible if either qualitative or quantitative studies only were included in the systematic review (McEvoy and Richards, 2006; Moffatt *et al.*, 2006).

Lastly, as this study is underpinned by a critical realist stance, I aimed to go beyond the empirical observation of service user outcomes to understand why reported outcomes did, or did not, happen. As one would expect, service users and health professionals reported that health related behaviour changes underpinned the experienced health and wellbeing improvements (White, Kinsella and South, 2010; Kimberlee *et al.*, 2014; Moffatt *et al.*, 2017). Several included studies identified that working with a navigator is a key enabler of behaviour change (White, Kinsella and South, 2010; Friedli, Themessl-huber and Butchart, 2012; Kimberlee *et al.*, 2014; Farenden *et al.*, 2015; Moffatt *et al.*, 2017). On-going support, motivation, and the development of open and trusting relationships appeared to improve the self-concept and independence of service users and made them feel prepared and ready to participate in the referred activities (Moffatt *et al.*, 2017). Additionally, motivation, continuous, and need driven support from navigators appeared to promote adherence to activities, which is likely to affect behaviour change and service user outcomes, too (Moffatt *et al.*, 2017). Based on these findings, navigators appear to be a key component of the SP pathway, and may partly explain how and why SP interventions work (Moore *et al.*, 2014). This conclusion is consistent with the findings of a recent study, based on critical realism,

which identified the navigator-service user relationship as one of the main mechanisms that enable SP to achieve behaviour change in service users (Bertotti *et al.*, 2017).

10.3 Discussion of objective 2

Objective 2 aimed to explore facilitators and barriers to the implementation of the Luton SP programme. Semi-structured interviews were conducted with navigators (N=4), GPs (N=3), service providers in the third sector (N=5), and managers/decision-makers (N=9). Thematic analysis was used to analyse the data. Following analysis, seven themes were identified: Operational processes, evaluation of the Luton SP programme, communication and relationships, shared knowledge and understanding, human resources, organisational readiness, and contextual factors.

Some identified factors affecting the implementation of the Luton SP programme were similar to the factors identified in the systematic literature review (Objective 1). These factors include the early engagement of stakeholders in the development of SP schemes, a multi-agency approach to management, service level and partnership agreements, programme adaptability, effective communication between stakeholders, inter and intra organisational relationships, shared knowledge and understanding among stakeholders, the importance of the navigator role, staff turnover, availability of local third sector resources, and navigator-ready surgeries. In line with the findings of the review (Objective 1), the primary study found complex interrelationships between the identified facilitators and barriers to the implementation of the Luton SP programme (Figure 13). However, this study found a range of factors that affected the implementation of the Luton SP programme and were not discussed in the national SP literature previously. For clarity, these factors are marked in blue in Figure 13. Thus, findings of this study contribute to the existing knowledge base in demonstrating factors that influenced the implementation of the Luton SP scheme.

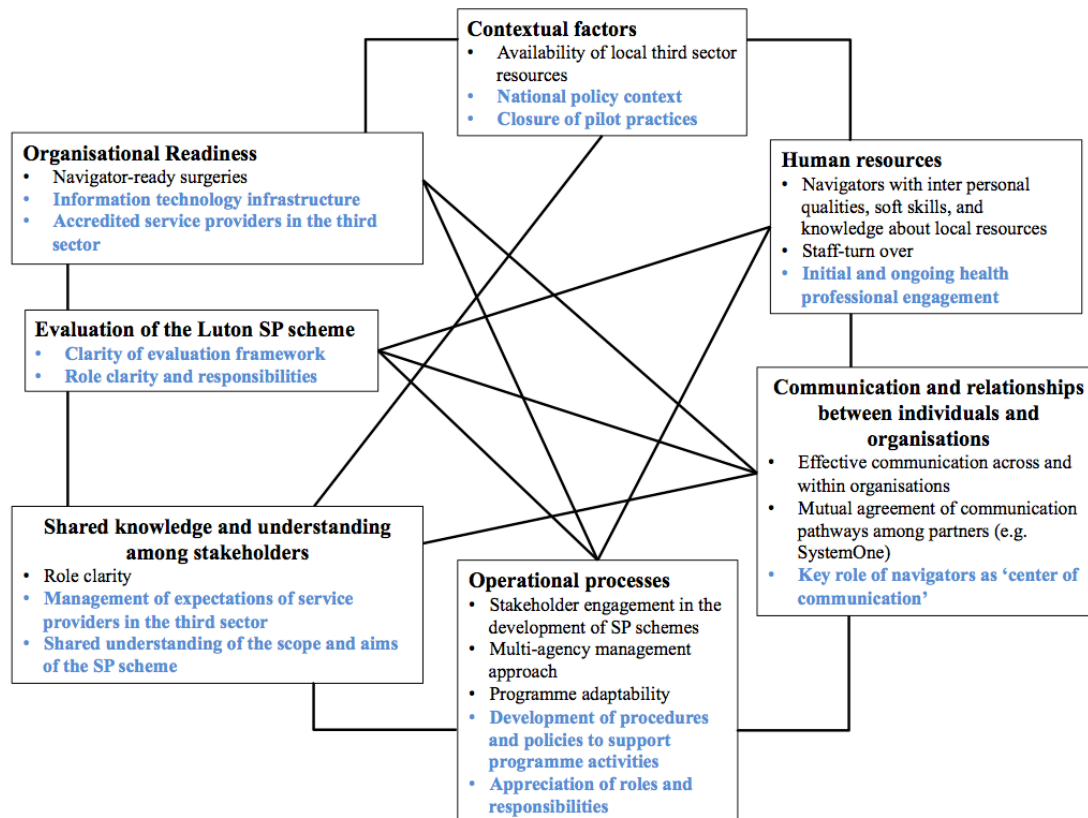


Figure 13: The interrelationship between identified factors influencing the implementation of SP programmes (Objective 2)

Consistent with the findings of Objective 1, the findings of this study are relevant to the multiple levels of integration outlined in the RMIC. To prevent repetition, factors not discussed in relation to the RMIC in Objective 1 will be discussed in this section only. A clear evaluation framework and the development of procedures and policies to support programme activities fall, for example, under *functional integration*, as they can promote *organisational and professional integration* (Valentijn *et al.*, 2013). *System integration*, for example, shared or compatible IT systems, is required for the development of a technological infrastructure supporting the delivery of SP programmes (Valentijn *et al.*, 2013). At the same time, shared IT systems can also fall under *functional integration*, as findings showed that they promoted effective communication between partners (e.g. navigators and GPs) (Valentijn *et al.*, 2013). Contextual factors, such as the national policy context, were found to influence the integration at a system and organisational level.

This study found that the externally developed and managed accreditation process in the Luton SP scheme was perceived as too complex, time consuming, and unclear. In addition, findings showed that service providers had difficulties in understanding specific terms such as ‘governance’ and lacked appropriate support and effective communication with the

responsible external company. In general, managers, navigators, and service providers, perceived the accreditation process as a barrier to implementation, as it hindered service providers to come on board or delayed their involvement in SP. To respond to the identified concerns and challenges with the outsourced accreditation process, the accreditation process was simplified (i.e. service providers were allowed to send the required documents via email to the programme manager instead of going through an external company and uploading the documents to an online platform). Responding to the early expressed concerns (i.e. programme adaptability) seemed to resolve the identified barrier. Whereas this study found that the original accreditation process hindered the implementation of the Luton SP scheme, previous research identified efforts to ‘quality assure’ the community resources that patients were being referred to as key factors for successful implementation and sustainability of SP services (Mossabir *et al.*, 2015; Whitelaw *et al.*, 2017). Interestingly, navigators, managers, and service providers (the end users) identified the initial accreditation process as a barrier in this study. Previous research found that quality-assured services are important for GPs to know that they could confidently refer their patients into safe and reliable community services (Whitelaw *et al.*, 2017). Referring to non-NHS services of unknown quality was identified as a major barrier to health professional engagement in SP (Whitelaw *et al.*, 2017). These findings indicate that a clear, simple, and understandable accreditation system for service providers may support organisational integration and professional integration, often hindered by the lack of trust and differences between professional groups and organisations (RAND Europe, 2012; Valentijn *et al.*, 2013; Mackie and Darvill, 2016; White, Cornish and Kerr, 2017). Therefore, the quality-assurance of third sector resources is an example of *functional integration* in the RMIC. In addition, the findings highlight the importance of exploring and considering the perspectives of multiple stakeholder groups in the development and implementation of operational processes in integrated care.

Similar to this study, previous research found that inappropriate referrals from GPs to navigators hindered the implementation of SP (White, Kinsella and South, 2010; Mossabir *et al.*, 2015). Navigators of the Bradford SP scheme suggested that GPs refer some patients to SP because the waiting times to see mental health staff were long (White, Kinsella and South, 2010). Findings of this study revealed that often the complexity of cases and whether patients are eligible for SP, or not, becomes clear after the first appointments with navigators. Due to the uncertainty of available support for ‘inappropriate’ patients beyond SP, navigators in the Luton programme tended to work with this patient group. In addition, findings revealed that navigators’ decisions are driven by their emotions and fears of letting patients down. However, working with patients whose needs are beyond the scope of SP may risk the sustainability of the service and the achievement of intended outcomes. In the literature, the

described pathways of SP holistic models based in primary care do not include a pathway for patients who are referred to SP by GPs and are identified as ‘inappropriate’ by navigators. Furthermore, the prevalence and reasons for inappropriate referrals and how navigators dealt with them are neglected topics in the literature to date. Thus, in addition to an identified barrier (i.e. inappropriate referrals) to implementation and sustainability of SP, this study highlights a knowledge gap that requires further attention in research and practice.

In the Luton programme, the development and delayed implementation of the shared IT system was identified as a major barrier to implementation. The ‘paper based’ approach hindered accessing and sharing data between front-line providers, aggravated continuous communication, and the efficacy of the integrated teams. In addition to unanticipated challenges, the lack of clear processes, shared understanding of roles and responsibilities, and communication issues hindered the development of the required technological infrastructure (Figure 13). Interestingly, the development of a shared IT system was not cited as a barrier to the implementation for other SP services in the UK. This may be explained by the lack of implementation research in this field, as identified in this study’s systematic review (Objective 1). However, consistent with the findings of this study, the development of shared IT systems between social and healthcare organisations was identified as a challenge in the integrated care literature (Ling *et al.*, 2012; Cameron *et al.*, 2014; Maruthappu, Hasan and Zeltner, 2015; Mackie and Darvill, 2016; Baxter *et al.*, 2018). Incompatible IT systems, maintaining patient confidentiality, GP reluctance to share patient data due to privacy concerns, no existing data sharing agreements between health and social organisations, and issue with a software’s licensing policy and information governance were identified barriers to shared IT systems between health and social care (Ling *et al.*, 2012; Mackie and Darvill, 2016). This study also found that the process of getting a NHS Smartcard for navigators (i.e. non-NHS staff), delayed the implementation and delivery of the service in two practices. Uncertainties in who is responsible for navigators, bureaucratic structures, poor communication, and the lack of clear procedures contributed to these delays (Figure 13). The existing gap between the technological infrastructure across sectors reflects the traditional division between health and social care in the biomedical approach to clinical practice, which focused on biological factors without much regard for psychosocial elements of health and illness (Fava and Sonino, 2017). However, in line with the RMIC, findings highlight that in addition to human, financial, and tangible resources (i.e. space for navigators), appropriate technological resources (i.e. integrated information technology) are key facilitators to implementation and robust evaluations of SP. This finding demonstrates that the shift towards the biopsychosocial model of care not only require changes in human behaviour and

perspectives, clinical practice, organisational cultures, policies, and funding streams, but also in the technological infrastructure.

10.4 Discussion of objective 3

Objective 3 aimed to explore factors that affect service user uptake and adherence to the SP programme in Luton. Semi-structured interviews were conducted with ten service users. Thematic analysis was used to analyse the data. Following analysis, five themes were identified for uptake: Trust in GPs, perceived need and benefits, programme design, patient expectations, and stigma of psychosocial problems; and five themes for adherence: Navigator's role, support, availability and accessibility of services, perceived benefits, and health and wellbeing.

Out of the ten interviewed service users, nine were women. Hence, male service users were underrepresented in the study sample, which is a potential source of gender-bias (Markanday *et al.*, 2013). If gender bias is not acknowledged, findings from a study of mainly one sex may be falsely generalised and applied to both (Holdcroft, 2007). Therefore, it has to be acknowledged that the qualitative evidence on factors affecting uptake and adherence to SP has been obtained mainly from women in the present study. One explanation for the unbalance in gender in the study sample (9 women, 1 male) may have been an unbalance in the overall study population. The descriptive analysis of the quantitative data (Objective 4) showed that almost twice as many women than men were referred to the Luton SP programme. However, as navigators did not report the dropout rates, the gender of approached service users, and reasons for non-participation in the study, it remains unclear why women are overrepresented in this study sample.

The findings identified that factors at the following three levels affected service user uptake and adherence: Service user related factors, programme related factors, and contextual factors. In this study, service user related factors are defined as factors related to the individual, such as beliefs, health status, and support from family and friends, which are out of the programme's control, but influence uptake and adherence to SP. Programme related factors are defined as factors that are directly related to the SP programme, such as programme design, the role of navigators, and service providers, which influence uptake and adherence to SP. Contextual factors are defined as pre-existing conditions in the setting of the programme, such as social and political environments and available community resources, which are out of the programme's control, but influence uptake and adherence. Table 32 outlines the identified themes by these three factors.

Table 32: Identified themes by service user related, programme related, and contextual factors

	Service user related factors	Programme related factors	Contextual factors
UPTAKE	Trust in GPs	Programme design	
	Perceived need and benefit		
	Patient expectations		
	Fear of stigma of psychosocial problems		
ADHERENCE	Support (family and friend)	Navigator role	Availability and accessibility of services
	Accessibility of services	Support (Navigators and service providers)	
	Experienced benefits		
	Health and wellbeing		

Uptake

Trust in GPs is a factor affecting the uptake of SP at the individual (patient) level. Consistent with previous research, trust in GPs who initiate the referral to SP was identified as a key factor promoting patient uptake (Bertotti *et al.*, 2017). The doctor-patient relationship is likely to be influenced by the model that dominates healthcare at any given time (Kaba and Sooriakumaran, 2007). In the historically dominant model of healthcare, the biomedical model, the doctor-patient relationship was based on a patient seeking help to treat illness and a doctor deciding on a medical intervention to restore the patient's health or decrease pain (Kaba and Sooriakumaran, 2007). As discussed in Chapter 2 of this thesis, the paternalistic model of the doctor-patient relationship has undergone a transition over the past decades. With the rise of the biopsychosocial model of healthcare since the 1990s, a patient-centred approach to medical care became more prominent (Kaba and Sooriakumaran, 2007; Farre and Rapley, 2017). Besides the transition towards a more equal doctor-patient relationship in which patients have a more active and autonomous role, findings of this study indicate that GPs are considered as powerful and trusted individuals in our society. This view may stem from the doctor-patient relationship in the traditional biomedical model of healthcare, which still dominates Western healthcare systems (Edozien, 2015). Patients' trust in GPs may be both rooted in the traditional biomedical model of healthcare and, as identified in this study, a key factor promoting the uptake of SP interventions, based on the 'new' biopsychosocial model of healthcare. Thus, the doctor-patient relationship may play a key role in the rise of the biopsychosocial model, and the patient uptake of non-medical interventions such as SP.

This study identified perceived needs and potential benefits of SP as another factor at the individual level promoting the uptake of SP. This is consistent with previous studies that identified the lack of perceived need as a barrier to the uptake of SP (Carnes *et al.*, 2017). Interestingly, this study found that some patients understood their needs and potential benefits of SP after the GP has pointed them out in the consultation. Again, this indicates that the doctor-patient relationship plays a key role in understanding potential benefits for patients, and therefore the uptake of SP. In addition, this highlights that *clinical integration* (i.e. the extent to which patient care services are coordinated across various professional, institutional, and sectorial boundaries in a system), a domain in the RMIC, is determining the uptake of SP (Valentijn *et al.*, 2013). *Clinical integration* requires health professionals to consider biological, psychological, behavioural, and social factors contributing to illness and poor wellbeing, rather than relying only on biological factors to understand health and illness (Valentijn *et al.*, 2013; Edozien, 2015). Additionally, it includes the provision of understandable and clear information about the wider determinants of health at the individual patient level, which as found in this study, promotes patient uptake of SP. Thus, findings indicate that in addition to healthcare professionals, it is important that patients too understand the interplay of biological and non-biological factors in shaping their health, illness, and wellbeing and the potential benefits of SP to address their non-medical problems.

Consistent with the findings of the systematic review (Objective 1), findings of this qualitative study identified that patients' expectations of being referred to medical interventions, rather than to SP, may create a potential barrier to uptake (Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; Whitelaw *et al.*, 2017). Patients' expectations are likely to be influenced by the traditional biomedical model of healthcare. Since the 1990s, the shift from the concept of the biomedical model of healthcare to the biopsychosocial one, has influenced core aspects of medical practice, education, and research (Farre and Rapley, 2017). Despite the uneven and slow uptake of the biopsychosocial model in practice, as discussed in Chapter 2, its concepts are increasingly included in guidance and policy documents (Edozien, 2015; Farre and Rapley, 2017). Integrated care is a clear policy priority in the UK today and integrated care initiatives, such as SP, are increasingly funded and implemented. However, the findings of this study highlight that in addition to research, policy, medical practice, and education, a shift in the perspectives of patients (i.e. end users) towards the biopsychosocial model of healthcare is required, too. If the transition is not happening in the patients' perspectives and their expectations of healthcare, despite the uptake by practitioners and policymakers, non-uptake at a patient level may turn into a significant barrier to interventions based on the biopsychosocial model, such as SP. The

findings support the concerns raised by Smith (2002), that the ‘biopsychosocial revolution’ may be hindered if the relevant biopsychosocial understanding of patients is not achieved.

In this study, the SP pathway, in which navigators initiate the first contact with patients after referral, was identified as a factor promoting patient uptake. Similar to previous research, findings identified that patients did not always understand SP and the reason for their referral prior to the navigator contact (Faulkner, 2004; Brandling *et al.*, 2011; Bertotti *et al.*, 2017). This study found that the initial phone call from the navigator served as a reminder about SP and provided the opportunity for referred patients to clarify their questions and understand the purpose of their referral. This part of the pathway supports clinical integration (Valentijn *et al.*, 2013).

Adherence

The qualitative analysis demonstrated the critical role of the navigator in facilitating adherence to SP. This finding is consistent with previous research on SP programmes (Friedli, Themessl-huber and Butchart, 2012; Bertotti *et al.*, 2017; Moffatt *et al.*, 2017; Woodall *et al.*, 2018) and wider linking schemes from healthcare providers to community resources (Mossabir *et al.*, 2015). Participants in this study reported a wide range of navigator characteristics that promoted their adherence to SP, including knowledge about local non-medical resources, active listening and good communication skills, tailoring activities to the needs and preferences of participants, and being patient, empathetic, approachable, flexible, and trustworthy. Thus, as also acknowledged by other researchers, the navigator’s role is complex and requires a mix of mainly soft skills outside clinical knowledge (Bertotti *et al.*, 2017; Woodall *et al.*, 2018). Although the navigator role was classified as a ‘programme related factor’ affecting adherence to SP for this discussion, it may be challenging to control the required skills and characteristics of navigators, as interpersonal qualities cannot easily be trained and objectively assessed. At present, the background and training of navigators varies between SP programmes, however, most navigators have a social or psychological background and have worked with vulnerable people before (Bickerdike *et al.*, 2017). It is worth noting that the shift from the biomedical to the biopsychosocial model of healthcare contains a shift in the knowledge and skills of providers too. In addition to the clinical knowledge of healthcare professionals, that can be trained and objectively assessed, providers with a mix of soft skills and non-clinical knowledge (i.e. integrated skills and knowledge) are required to assess and respond to the medical and non-medical determinants of health in the biopsychosocial model of healthcare.

Support was identified as another key factor promoting the adherence to SP in this study. Support for service users from the following three sources were identified as factors affecting adherence to SP: Family and friends, navigators, and third sector organisations. Whereas the provided support from navigators and service providers are directly related to the SP programme, the available support from family and friends are out of the programme's control. The qualitative findings of this study can partly explain why the support of navigators can facilitate the adherence to SP. This study found that the navigator's ability to understand and address potential barriers to engagement is critical to adherence to SP programmes. For example, the identified 'two-step approach', meaning that navigators initially referred service users to activities that helped them to prepare and feel able to eventually engage with activities addressing their non-medical needs, seems to facilitate the long-term engagement of service users. In addition, this study identified the navigator's company to referred activities as a major factor promoting initial engagement in referred services. Accompanying service users is based on *clinical and professional integration*, as providers across sectors need to communicate and collaborate to provide continuous support and care to service users across sectors. Just as the support from navigators, the support from service providers in the third sector was identified as a key determinant of adherence. Support of service providers promoted adherence, whereas the lack of support, understanding, and response to service users (i.e. no *clinical integration*) was identified as a major barrier.

Lastly, accessibility and availability of services in the third sector, experienced benefits by service users, and the health and wellbeing of service users were identified as factors affecting adherence to SP, however, all three are beyond the programme's control. However, the accessibility of services is also affected by personal factors. Some service users reported that they couldn't access services because they couldn't afford the transport to the activities, have mobility issues, or feel uncomfortable to leave their familiar area (individual level factors). On the other hand, this study found that third sector organisations can be difficult to reach by public transport, may lack close parking facilities, or may not be available outside of working hours, thus contextual factors may hinder adherence to SP too. Together, the findings of Objective 3 suggest that uptake and adherence to SP is affected by the interactions between the patient/service user and the three stakeholder groups along the SP pathway (GPs, navigators, third sector organisations), service user related factors, programme related factors, and contextual factors.

10.5 Discussion of objective 4

Objective 4 aimed to assess and explore the impact of SP on service users. A mixed methods approach was applied, including ten semi-structured interviews with service users and

quantitative analyses of a change in mental wellbeing and energy expenditure, using secondary data. Following thematic analysis of the qualitative data, the following three themes were identified: Health related behaviours, mental wellbeing, and pain relief. The same service users (N=10) were interviewed for objective 3 and 4, therefore, it has to be acknowledged that most qualitative data on service user outcomes were collected from female participants (Table 13).

10.5.1 Qualitative findings

Consistent to the findings of the systematic review (Objective 1) the qualitative findings identified that some service users have experienced positive health related behaviour changes, reflected in increased levels of physical activity and improved dietary habits (White, Kinsella and South, 2010; Dayson and Bashir, 2014; Kimberlee *et al.*, 2014; Moffatt *et al.*, 2017). Participants reported that these changes have impacted positively on their mood, weight loss, energy levels, feelings, and daily functioning. Similar to the findings of the systematic review (Objective 1), the support and motivation of navigators and service providers were identified as important contributors to the achievement of positive outcomes. This may be due to the fact that, as found by objective 3, navigators and service providers play a key role in behaviour changes and adherence to onward referrals. In contrast to other qualitative studies, this study reported that some service users did not engage with the referred physical activities, and thus did not change their physical activity level (White, Kinsella and South, 2010; Dayson and Bashir, 2014; Kimberlee *et al.*, 2014; Moffatt *et al.*, 2017). Moreover, this qualitative study is novel in considering both short-term and long-term outcomes for service users. Whereas service users reported to experience increased physical activity levels and improved dietary habits while being enrolled in SP, these improvements were not maintained after the end of prescribed activities. Interestingly, not being able to afford the gym membership or personal training sessions (including dietary advice) to continue the activities initially offered by SP, was identified as a major barrier to maintain health related behaviour changes. Although findings of objective 3 indicate that free services may promote uptake of SP, it became apparent that free services could lead to the discontinuation of the adopted behaviour, if individuals cannot afford to continue activities beyond SP. Similarly, previous research found that financial incentives (e.g. free gym memberships) to increase physical activity levels in adults were effective only on the short-term, as after ending the incentive the adopted physical activity behaviour were discontinued (Barte and Wendel-Vos, 2017).

Similar to previous research, the majority of service users experienced improvements in their mental wellbeing due to SP (White, Kinsella and South, 2010; Dayson and Bashir, 2014; Kimberlee *et al.*, 2014; Moffatt *et al.*, 2017). Consistent to the findings of the systematic

review (Objective 1), this study found that the appointments with the navigators alone contributed to improved mental wellbeing of some service users (Bertotti *et al.*, 2017). In contrast to complex behaviour changes that require lifestyle changes (e.g. physical activity), positive effects on mental wellbeing appeared to be maintained on a long-term. The majority of service users applied the acquired skills, such as coping strategies to reduce stress, anxiety, or panic attacks, on a regular basis to maintain and further improve their mental wellbeing after ending SP. Moreover, those service users who discovered a new creative hobby through SP, for example painting or decorating cards, continued with it independently from SP in their free time.

Whereas findings indicate that massage therapy, while enrolled in SP, reduced shoulder pain on the long-term (six months) for one service user (Service user 7), it resulted in only short-term (immediately after the intervention) low back pain reduction for another service user (Service user 5). Due to financial constraints, the service user wasn't able to afford the massage therapy after the end of SP, and reported to be in severe pain and feeling depressed three weeks after the end of SP. Given that this research is based on the critical realist philosophy, I aimed to understand why, or why not, outcomes might have happened. The negative outcome may be explained by the nature of the onward referrals. As shown in Table 14, the massage therapy was the only reported onward referral to manage the service user's back pain (Service user 7), which was the primary reason for the referral to SP. The existing literature documents massage therapy as an effective non-medical treatment to relief back pain (Kamali *et al.*, 2014; Ooi, Smith and Pak, 2018). However, findings of this study are consistent with previous research that found that massage therapy is an effective treatment for lower back pain in the short-term (Furlan *et al.*, 2015; Kumar *et al.*, 2017). Furthermore, it is questionable to what extent the onward referral to massage therapy only is in line with the underlying aim of SP to empower service users and encourage them to take control over their health and wellbeing. Secondly, the appropriateness of referrals to SP needs to be considered, as treating back pain is beyond the scope of the Luton SP programme (Koes *et al.*, 2018). SP may be more appropriately used to address cognitive (e.g. catastrophic thoughts, poor motivation), psychological (e.g. low mood), social (e.g. low job satisfaction, interpersonal relationship stress), and lifestyle (e.g. physical inactivity) factors acting as catalysts for lower back pain and poorer recovery, and to learn pain coping skills, rather than focusing directly on clinical outcomes such as pain relief by providing massage therapy (Synnott *et al.*, 2015; Koes *et al.*, 2018). This finding highlights the importance of shared understanding among GPs, patients/service users, and navigators of the scope and aims of SP, to ensure that the SP service has the capacity to achieve service users' expected outcomes and is utilised as intended. As the systematic review of this study (Objective 1) and by Bickerdicke *et al.*,

(2017) showed, SP programmes can be related to a wide range of personal and interrelated outcomes. However, in order to prevent misleading conclusions it is important to interpret reported successful and unsuccessful outcomes in the light of the aims and scope of a SP programme in qualitative outcome studies.

10.5.2 Quantitative results

Mental wellbeing

Following quantitative analysis of the SWEMWBS data, a statistically significant increase in mental wellbeing was identified. As the SWEMWBS is designed to measure mental wellbeing, there is no clinical cut off for this measure (Morton, Ferguson and Baty, 2015). However, the mean increase identified in this study is slightly below the three points difference at the SWEMWBS (Mean difference=2.78, 95% CI 1.68, 3.88), considered as clinically relevant. Thus, the clinical relevance of the change in mental wellbeing in the Luton cohort remains uncertain, but is unlikely to be relevant.

Previous research by Morton *et al.* (2015) found that 66.2% (N=90) of participants in SP were on antidepressant medication and 65.4% (N=89) reported that they were attending sessions with a psychologist or counsellor while attending SP. Given that the pathway of the SP programme evaluated by Morton *et al.* (2015) differs from the Luton model, as individuals can either self-refer to SP or be referred by any allied healthcare staff, for example psychologists, community practice nurses, and occupational therapists, it is possible that the sample characteristics are different. However, the qualitative research of this study found that mental health problems were prevalent in the interviewed cohort, too. As we don't know whether participants received therapeutic input or/and took anti-depressant medication while being enrolled in SP, it is not possible to establish whether attending SP alone contributed to the observed improvement in mental wellbeing.

The results also revealed that the mean SWEMWBS score for men and women in the Luton cohort is below the national average of 23.7 for men and 23.2 for women, both pre- and post-intervention (Table 20) (Ng Fat *et al.*, 2017). This may be explained by the potentially high prevalence of mental health problems and poor wellbeing in patients referred to the Luton SP programme. Additionally, the Health Survey for England in 2016 found that individuals living in more deprived areas in England, such as Luton, had on average lower wellbeing scores on the WEMWBS than those living in less deprived areas (Morris, Earl and Neave, 2017).

Contradictory to the results from this study, the study by Wiegfield *et al.* (2015) found no statistically significant difference in mental wellbeing, measured with the SWEMWBS, post-intervention. However, similar to the results of this study, previous research identified positive trends in mental wellbeing measured with the SWEMWBS (ERS Research and Consultancy, 2013) and WEMWBS (Age UK and Age concern, no date; Brandling *et al.*, 2011; Friedli, Themessl-huber and Butchart, 2012; Vogelpoel and Jarrold, 2014; Baines, 2015; Morton, Ferguson and Baty, 2015; Woodall *et al.*, 2018). Although these studies consistently indicate that SP may have the potential to improve mental wellbeing, results of the studies need to be compared with caution due to differences in methodologies, SP programmes, and implementation settings (Moore *et al.*, 2014). It is worth to acknowledge that previous studies that have used a paired t-test to assess the change in WEMWBS scores after SP programmes (i.e., uncontrolled before after studies) did not mentioned the assumptions of it (Morton, Ferguson and Baty, 2015; Woodall *et al.*, 2018). Therefore, it is unclear whether the data was checked against, and met, the assumptions of the paired t-test in previous studies.

Findings of the quantitative study are consistent with the findings of the qualitative study that SP has the potential to improve the mental wellbeing of service users. The ‘paper based’ nature of the programme, together with navigator turnover and delays in recruiting and training new navigators, hindered the initially planned follow-ups after three and six months of the exit interview. Therefore the maintenance of the observed change in mental wellbeing remains unclear on a long-term (three months, six months after the exit interview).

The descriptive analysis indicated that there are differences between the mean changes in the SWEMWBS score between genders, working status, and age groups. In general, there was an increase in mental wellbeing across genders, working status, and age groups, however, the magnitudes of change differed. It is worth noting that the average increase in SWEMWBS scores was almost twice as much for participants classified as not working, compared to those classified as working (Table 22). Considering the clinical relevance of findings, the mean difference in SWEMWBS scores for those not working may be considered as clinically relevant (mean difference=3.29), whereas the mean difference for those working may not (mean difference=1.77). This finding could be explained by the difference in baseline measures between sub-groups. Those not working had on average lower initial levels of wellbeing than those working (Table 22) and therefore were more points away to the national norm for mental wellbeing on the SWEMWBS, than those working (Ng Fat *et al.*, 2017). Another outstandingly high mean difference in SWEMWBS scores and clinical relevance was observed between the age group 34-43 years (mean difference=0.80) and 64-73 years (mean

difference=6). The results from this study contradict previous findings, with a greater variability between age groups in pre- and post-mean SWEMWBS scores (Ng Fat *et al.*, 2017; Woodall *et al.*, 2018). Although the reason for the observed variability between age groups remains unclear, these results contribute to the sparse evidence base on SP outcomes by socio-demographic characteristics of participants, and highlight the importance of subgroup analysis for future research.

Energy expenditure

The IPAQ-SF was used to collect quantitative data on physical activity levels at baseline and in the exit interview with navigators, hence, immediately after the end of SP. As the IPAQ-SF measures physical activity over the past seven days, it essentially measures the physical activity levels of service users over the last week of the enrolment period. Results found a positive trend in the change of energy expenditure between baseline and follow-up measures. In the Luton cohort, an increase in the average total energy expenditure (56.3%), and average energy expenditure from walking (41.7%), moderate level physical activity (5%), and vigorous level physical activity (107.3%) was expected post-intervention (Table 28 to Table 31). The evidence for these positive effects is strong (Table 28 to Table 31). The outstandingly high increase in energy expenditure from vigorous physical activity is difficult to explain and may be subject to data entry error during data collection. Those service users who were inactive when starting SP (i.e. stated not to do any walking, moderate, or vigorous physical activities for at least ten minutes at a time over one week) had a 25%, 23.5%, and 6% increase in the probability of observing energy expenditure from walking and moderate physical activity, accordingly, at the end of the SP programme. There is strong evidence for a positive effect (i.e. increase) in the probability of observing non-zero MET scores for walking and moderate activity post-intervention, but the evidence is unclear for vigorous activity (Table 28 to Table 30). In total, participants who stated to be inactive at baseline had a 26.4% increase in the probability of observing energy expenditure from any activity level at the end of the SP programme. There is strong evidence for this positive effect (Table 31).

It is difficult to judge the overall clinical relevance of the observed percentage increases in energy expenditure per week. However, previous research concludes that small increases in energy expenditure (100 to 200 kcal/day) may be sufficient to prevent gradual weight gain in adults (Hills *et al.*, 2013; Ross *et al.*, 2016; Basolo *et al.*, 2018). Moreover, there is good evidence that regular physical activity reduces the risk of the development of chronic conditions, such as CVD and type 2 diabetes, (Booth, Roberts and Laye, 2012; Durstine *et al.*, 2013; Marques *et al.*, 2018). In addition to primary prevention, previous research demonstrated that physical activity can improve quality of life, mental health, and plays an

important role in secondary prevention of chronic conditions by reducing the impact of the disease, slowing its progress, and preventing recurrence (Karmisholt and Gotzsche, 2005; Saxena *et al.*, 2005; Herring, O'Connor and Dishman, 2010; Durstine *et al.*, 2013; Alves *et al.*, 2016). The quantitative analysis has also found that the SP programme has the potential to promote physical activity in inactive patient groups. The qualitative findings of this study (Objective 3) support this quantitative finding. Service users who did not engage in any physical activities at the point of referral, and did not feel they could do so by their own, stated that the SP programme helped them to start getting physically active after long periods of inactivity. It is worth acknowledging that data on physical activity were collected routinely for all referred patients, independently from the reasons for referral and type of onward referrals. As discussed in Chapter 6, it was originally planned to conduct sub-analysis by including only those service users who aimed to increase their physical activity levels and/or were referred to physical activities. However, due to the delays of the IT system, and resulting challenges to data collection (discussed in detail in Chapter 6, section 6.4.2), the sub-analysis could not be conducted. Therefore, it is possible that the results underestimate the average increases in energy expenditure and probability of observing a non-zero value for inactive individuals at baseline, at the end of the SP intervention. However, we have no information whether service users participated in interventions or activities promoting physical activity while being enrolled in SP, thus it is not possible to establish from these findings whether attending SP alone contributed to the observed changes in energy expenditure.

Previous evaluations assessing the change in physical activity levels of service users after a SP intervention found mixed results (Kimberlee *et al.*, 2014; Wigfield *et al.*, 2015). The evaluation by Wigfield *et al.* (2015) found no statistically significant change in 'Minutes walking a day', 'Minutes of hard breathing exercise per week', and 'Minutes of muscle strengthening activity per week' at three months follow-up. The study by Kimberlee *et al.* (2014), found a statistically significant increase ($p\text{-value} < 0.05$) in the frequency of mean days on which individuals (i) walk more than ten minutes and (ii) do moderate exercise for 30 minutes, at three months follow-up (data collection tool: 27-item IPAQ) (Kimberlee *et al.*, 2014). No statistically significant change was observed for the frequency of vigorous physical activities between baseline and follow-up mean day scores (Kimberlee *et al.*, 2014). Although the study by Kimberlee *et al.* (2014) and the current study found an increase in walking and moderate exercises post-intervention, results cannot be directly compared due to different methods of analysis (frequentists vs. bayesian approach), outcome measures (mean day scores vs. MET minutes/week), delivery models, and lengths of follow-up periods (three months following enrolment in SP vs. end of SP programme usually after 12 sessions of referred activities).

The results of the quantitative study are consistent with the qualitative findings of the study that SP may have the potential to increase physical activity levels on a short-term. However, due to the barriers discussed earlier, no follow-up measurements were taken, and consequently results of this study are limited to the physical activity levels in the final week of enrolment with SP. The potential long-term effect (more than three months) of SP on physical activity remains unclear.

This study is the first to evaluate the trends between covariates (gender, age, working status) and energy expenditure in relation to SP programmes. Therefore, it adds to the sparse knowledge of the effect of covariates on service user outcomes of SP. The study found a negative association between age and energy expenditure from any physical activity level (i.e., older individuals have lower expected MET scores). Similarly, working status had a negative effect on energy expenditure in all but one MET level (i.e., working individuals tend to have lower expected MET scores, though evidence was unclear for moderate physical activity). No consistent pattern was observed across physical activity levels in the association between gender and energy expenditure (i.e., males have higher expected Walking and Total MET scores, whereas females have higher Moderate and Vigorous MET scores).

It is worth noting that the aims of the quantitative research of this study were not aligned with those of positivist researchers to produce objective results that can be generalised across time, settings, and populations (Johnson and Onwuegbuzie, 2004; Zachariadis, Scott and Barrett, 2013). Instead, following the critical realist perspective, this study aimed to produce an understanding of patterns and trends in the data for the Luton cohort, which are assumed to be influenced by the delivery model, setting, implementation process, involved individuals, and the dimensions outlined in the RMIC (Damschroder *et al.*, 2009; Moore *et al.*, 2014; Valentijn, Biermann and Bruijnzeels, 2016). Nevertheless, results can inform policy-makers, commissioners, and providers about the potential impact of SP holistic models, while considering that mental wellbeing and energy expenditure related outcomes might vary across them.

10.6 Study limitations

There are some important study limitations to discuss. Some of these limitations became evident after the research journey had begun and progressed. It is worth to note that the primary research focused on a ‘real-life’ intervention, and therefore the recruitment of participants and data collection were sometimes influenced by practical barriers out of the

researcher's control. In reflecting on the study limitations, it is hoped that future research in this field will try to mitigate some of these limitations.

- GPs did not report those patients who refused to get referred to SP. Thus, it was not possible to identify and include this patient group in this study. Given the lack of available data, this study could not explore the reasons for non-uptake of SP from a patient perspective. However, to gain an insight about the potential barriers to uptake, participating GPs were asked about patients' reasons to refuse their referral to SP.
- Another limitation related to the service user sample is that service users with sufficient English skills to participate in the interview were eligible for this study only. This decision was made based on limited resources and time to complete this study. Thus, service users who could not speak English were excluded from the study. There is no data on the actual numbers of non-English speaking service users, and therefore, the size of this service user group is unclear.
- Navigators were selected to act as gatekeepers and helped to recruit service users for this study. Navigator turnover and delays in recruiting and training new navigators hindered the recruitment of participants. Restricting the gatekeeper role to navigators is a limitation of this study. Including service providers in the third sector as gatekeepers could have helped in overcoming barriers to the recruitment of service users.
- A limitation of using secondary data is that data collection is outside of the researcher's control, and therefore may be prone to reduced quality and error. The absence of an IT system to collect and manage data in the Luton SP programme resulted in the lack of standardised reporting and incomplete data collection. As discussed in detail in Chapter 6 of this thesis, not all collected data could be included in the analysis as initially intended, due to too great diversity in reporting. Another limitation of the secondary data is that no information was collected on service users' medication intake, psychological input, or engagement with interventions/actions to increase physical activity while being enrolled in SP.
- The IPAQ-SF has also limitations that need to be considered. A limitation of the self-reporting questionnaire is that subjective measures rely on relative intensity, rather than absolute intensity captured with objective instruments such as accelerometers (Shook *et al.*, 2016). For example, fit individuals perceive the same activity

differently than unfit individuals due to the differences in the relative intensity (Jetté, Sidney and Blümchen, 1990; Shook *et al.*, 2016). Furthermore, in the compendium of physical activity, different physical activities are coded with a wide range of MET values based on intensity, for example, aerobic dancing 4-9 METs, gardening 3-7 METs, ball games 3-9.8 METs, bowling 2-4 METs, and housework 2-7 METs (Ainsworth *et al.*, 2011). In accordance with the recommended guidelines (IPAQ Research Committee, 2005), a single MET value per activity group (3.3 METs for walking, 4 METs for moderate activity, and 8 METs for vigorous activity) was used to calculate MET minutes/week from the IPAQ-SF data for the analysis, not accounting for different MET values within activity groups (Mansoubi *et al.*, 2015; Tierney, Fraser and Kennedy, 2015). In addition to the differences in MET values between activities, studies have found significant differences in MET values between healthy weight and overweight individuals during all activities (Mansoubi *et al.*, 2015). Using average MET values to estimate energy expenditure may result in an underestimation of energy expenditure in heavier individuals and overestimation of energy expenditure in lighter individuals (Spadano *et al.*, 2003). Therefore, using a standardised equation, which is not adjusted for personal differences is likely to result in an inaccurate measures of MET minutes/week from the IPAQ-SF (Spadano *et al.*, 2003; Tierney, Fraser and Kennedy, 2015; Gault, Elisabeth and Willems, 2017). Lastly, instead of stating the frequency and intensity of physical activities over the past seven days, service users often reported 'not sure'. This indicates that, as with other self-reported questionnaires, subjectively measuring behaviour over a period of time may be subject to recall bias (Fransson *et al.*, 2008; Tierney, Fraser and Kennedy, 2015).

- A limitation of the quantitative study is that the vast majority of participants were lost to follow-up or did not engage with the service after the initial appointment with navigators and therefore did not complete post-measures. Due to poor reporting (this is discussed in detail in Chapter 6), it remains unclear whether participants did not engage with the service after the initial appointment with the navigators, did not engage with the onward referrals, or if they completed the programme without completing the post-measures. Thus, in line with most studies of SP (Bickerdike *et al.*, 2017; Carnes *et al.*, 2017; Woodall *et al.*, 2018), the lack of consistent data on the number of people (i) referred to SP, (ii) declined to be referred to SP, (iii) attending an initial appointment with a navigator, and (iv) attending referred activities is a limitation of this study.

10.7 Chapter summary

This chapter has discussed the findings and results for objective 1, 2, 3, and 4. The systematic review (Objective 1) identified facilitators and barriers both similar to other integrated care programmes and specific to SP. The found interrelationships between identified factors affecting the implementation of SP programmes were visually presented. The review also found a discrepancy between quantitative and qualitative findings of service users outcomes. Moreover, it highlighted the weaknesses of previous evaluations, to support the development of a stronger evidence base for SP. Objective 2 provided valuable insights into facilitators and barriers to the implementation of the Luton SP programme and how they compare to the national literature. Moreover, it addressed the identified gap in implementation research for SP. Objective 3 contributed to the sparse evidence base on factors affecting patient uptake and adherence to SP. It highlighted that patient related, programme related, and context related factors could influence uptake and adherence. Lastly, objective 4 presented the qualitatively and quantitatively measured service user outcomes of the Luton SP programme. Findings of the qualitative research highlight the importance of longitudinal studies to understand the long-term effects of SP. Moreover, by including covariates in the quantitative analysis, trends became evident in the secondary data, demonstrating the importance of covariates in future research. Lastly, this chapter ends with a discussion of the study limitations.

11 Chapter 11: Conclusion

11.1 Introduction

This final chapter concludes this thesis, presenting the study contribution to implementation, practice, and evaluation of SP and the recommendations and suggestions for policy and practice, research, and education.

11.2 Implementation and practice of SP

The findings of this study support the assumptions outlined in the RMIC (Figure 5) that the implementation and delivery of an integrated care intervention, such as SP, requires clinical, professional, organisational, and system integration (for a detailed description of the RMIC see section 4.2.2). It is important to highlight that the lack of integration at any level can hinder implementation and delivery, both on a short- and long-term. The primary and secondary research found a wide range of factors influencing the implementation and delivery of SP programmes in primary care. Informed by a critical realist perspective, the analyses revealed that the identified factors are interrelated, across levels and sectors (see Chapter 10). These complex interrelationships make it challenging to prioritise factors in the implementation and delivery process, as they cannot be seen in isolation. Thus, the implementation and delivery of SP should be perceived as a dynamic, complex, and constantly changing process, rather than a linear one based on a checklist exercise. However, this network of facilitators and barriers, and possible chain reactions, can activate or prevent mechanisms to successfully and sustainably implement and deliver SP. In addition, favourable contextual conditions can also activate such mechanisms. Although this study found that contextual factors play an important role in the implementation, practice, and outcomes of SP interventions, context is not considered in the RMIC. To address this limitation of the RMIC, the model could be placed in the ‘intervention context’, as demonstrated in Figure 14.

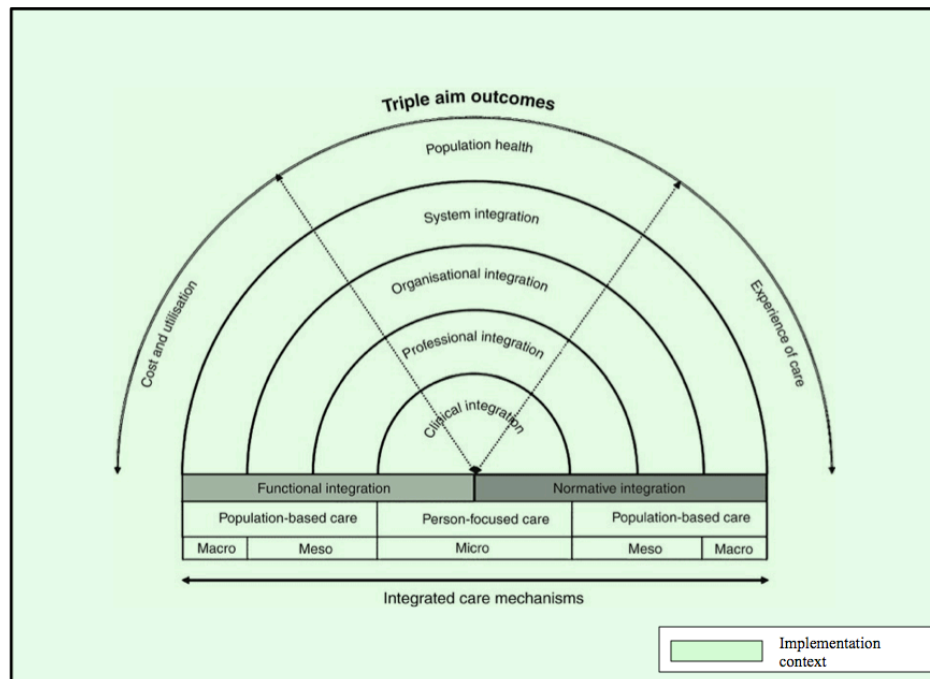


Figure 14: The revised RMIC (Valentijn, 2016) placed in the implementation context

It is important to understand that in complex interventions such as SP, mechanisms are not activated via an on/off switch and result in a binary outcome (successful vs. unsuccessful implementation/ delivery/ outcomes). Instead, activation operates along a continuum, where intensity varies with an evolving context and interaction of facilitators and barriers (Dalkin *et al.*, 2015). This study found that a key mechanism triggering smooth and sustainable implementation and delivery is shared understanding of the programme, roles, and responsibilities among stakeholders. Findings also revealed that a supporting policy context, a phased implementation approach, and the use of service level and partnership agreements strengthen shared understanding among stakeholders and, therefore, intensify this mechanism. Shared understanding, in turn, promotes effective communication between stakeholders, partnership working across sectors, and maintenance or development of new relationships. All these features are important to achieve clinical, professional, organisational, and system integration as outlined in the RMIC. Figure 15 demonstrates this process.

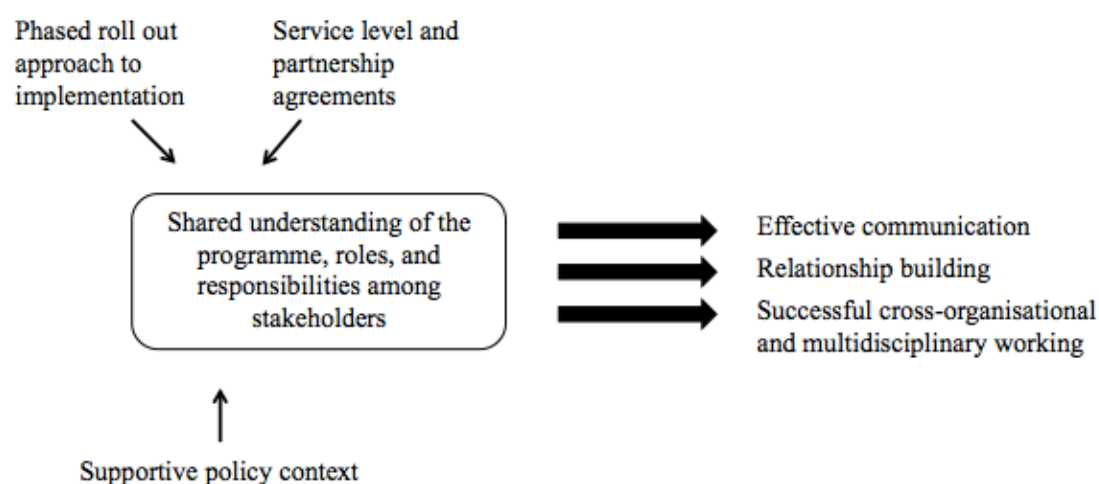


Figure 15: Key mechanism that triggers successful implementation and delivery of SP

This study also identified a key mechanism that may partly explain patient uptake of SP. Findings revealed that the GP-Patient relationship, based on trust, promotes patient uptake of SP. GPs are trusted figures in our society, a perception that may be rooted in the biomedical model and traditional recognition of doctors. Findings showed that patients' trust in GPs is transferred to the SP programme and navigators at the point of referral, and therefore promoted uptake. This finding clarifies the important role of GPs in the SP pathway as 'referrers'. Figure 16 demonstrates this process.

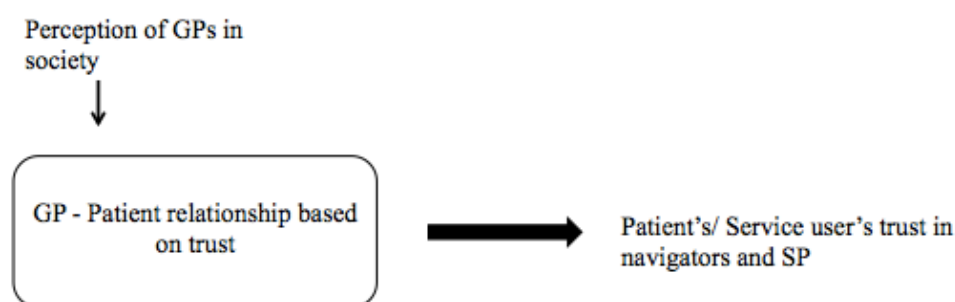


Figure 16: Key mechanism that triggers patient uptake of SP when referred by GPs

Another identified key mechanism that may explain the adherence of service users and observed changes in service user outcomes is the Navigator-Service user relationship. Consistent with this study, Bertotti et al., 2017 identified this relationship as a key mechanism that makes SP work. Continuous and need driven support and motivation from navigators were identified as major facilitators to uptake, continuous engagement with referred services (adherence), and behaviour change (outcomes). The skills and characteristics of navigators (e.g. empathetic listening skills, non-judgemental approach), as well as their co-location in the

surgery appeared to have an impact on their relationships with service users. Service users reported that they built their self-reliance, self-confidence, and independence during the interaction with navigators, so that they felt ready to engage with referred services in the third sector and to take control over their wellbeing. Figure 17 demonstrates this process.

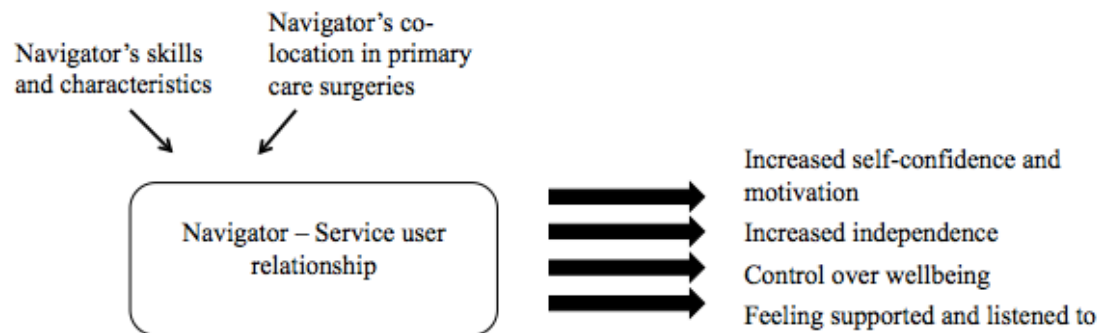


Figure 17: Key mechanism that triggers service user adherence and behaviour change

Finally, this study identified the ‘two-step approach’ applied by navigators as another key mechanism that promotes initial engagement with referred services, adherence, and positive service user outcomes. First, navigators identified and addressed potential barriers (e.g. low self-confidence, fear of the unknown) to the engagement in onward referrals. Introducing an extra step, rather than referring service users to sources of support when they are not ready to engage, promoted adherence and outcomes that could not have been achieved otherwise. Figure 18 demonstrates this process.

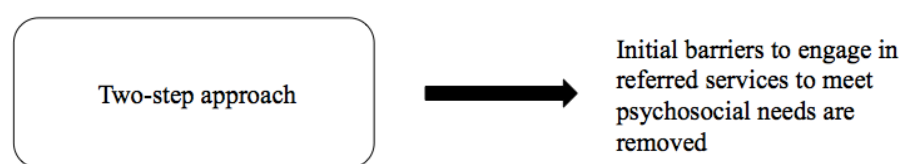


Figure 18: Key mechanism that triggers adherence and positive service user outcomes

The previously presented four mechanisms identified in this study are by no means fixed or exclusive. More research on potential mechanisms underlying the implementation and practice of SP is needed to develop a deeper understanding of why and how SP interventions work or do not work (Dalkin *et al.*, 2015; Lacouture *et al.*, 2015; Bertotti *et al.*, 2017).

11.3 Evaluation of the Luton SP pilot

System integration is not only necessary for the implementation and co-delivery of a SP programme, but also for its evaluation. In this study, a major barrier to robust evaluation was

the lack of a shared IT system between front-line providers (GPs (referrers), navigators, and service providers in the third sector). As discussed in Chapter 6 (section 6.4), it hindered complete and standardised data collection, long-term follow-ups, and increased the prevalence of errors in the data. In addition to communication issues with the producers and the lack of leadership, the traditional divide between the health and social sector, and resulting data protection and privacy issues, created a challenge for a shared IT platform. To overcome these challenges in the future and strengthen the evidence base of integrated care programmes such as SP, the technical infrastructure needs to change. To achieve this change, the NHS recommends robust data-sharing agreements between sectors and will be working with NHS Digital to introduce a consistent national coding for SP into existing primary care systems (NHS England, 2018).

11.4 Strengths and limitations of practice-based research

The practice-based research approach applied in this study had several strengths and limitations in relation to the Luton SP pilot, quantitative outcome measures, and transferability of findings. These will be discussed in the following sections.

11.4.1 The Luton SP pilot

Focusing the research on the local SP pilot in Luton had several benefits. Firstly, I was able to build relationships with stakeholders involved in the implementation and delivery of the Luton SP pilot. These relationships proved to be particularly beneficial at a later stage of the research process, as stakeholders understood the purpose of my study and were willing to participate in interviews and to assist in the recruitment of GPs, service providers, and users. The fact that the implementation of the pilot and my PhD study started at a similar time period enabled the parallel development of the pilot and the study. This also meant that I was present from the early planning phase of the pilot, which fostered my position in the team and resulted in a detailed and ‘insider’ understanding of the SP pilot’s development. As the Luton SP pilot was based in primary care, most of my primary research was conducted in this setting (interviews with navigators, GPs, and service users). The advantage was that the primary care surgery served as a hub for my research and provided a safe, accessible, and familiar place for participants.

The limitation of a practice-based approach to research, in contrast to an experimental one, is that the development of the pilot is out of the researcher’s control. As discussed in Chapter 6 of this thesis (see section 6.3.2), the resignation of navigators and technical challenges related to the NHS smartcard hindered the recruitment of service users and therefore delayed the research process. Furthermore, structural changes in the NHS and the retirement of the

practice manager aggravated the recruitment of GPs. To manage such ‘real life’ challenges, the continuous communication with the SP team, as well as my academic supervisors were key. In addition, a flexible approach to research and the PhD study was necessary, as my timeline and research plan had to be constantly adjusted to the development and changes of the SP pilot programme. Another challenge for practice-based research is that often practice ‘comes first’ and research ‘comes second’. An example from the current study is that once the new navigators were based in the surgeries (after significant delays), they focused on getting to know the service users and settling in their role, rather than collecting data and recruiting service users for research. In the case of SP, this challenge may be multiplied, as interviews found that decision-makers believe that the provision of ‘core primary care’ should be prioritised over the implementation and delivery of SP. If SP is perceived as ‘biomedical plus’ rather than a biopsychosocial model, SP research may not be regarded as a priority in primary care.

Data collection created another challenge in the Luton SP pilot. Navigators were responsible for the following data collection from service users: Socio-economic characteristics, the mental wellbeing score (at baseline and post-intervention using the SWEMWBS) and physical activity levels (at baseline and post-intervention using the IPAQ-SF). Throughout the pilot, navigators perceived data collection as an ‘add on’ to their role, rather than part of their role. The lack of clear understanding of navigators’ expectations from the outset (i.e. the job interview) resulted in consistent tension and resistance to research related tasks, such as data collection and recruitment of service users. The delays in the development of the IT platform further hindered standardised and complete data collection (see section 6.4.2). Thus, to overcome these tensions in a practice-based research approach, a clear evaluation framework and shared understanding of programme staffs’ research responsibilities from the outset are beneficial.

11.4.2 Outcome measures

Two quantitative outcome measures, SWEMWBS to measure mental wellbeing and IPAQ-SF to measure physical activity levels, were used in the Luton SP pilot. The selection of these measures was based on previous practice. Given the wide range of possible service user outcomes (see findings of systematic review section 7.2.4), the selection of pre-defined quantitative outcome measures for SP programmes creates a

challenge. As discussed in the introduction of this thesis (section 2.2.1), under the biomedical model, experimental research designs, such as a RCTs, were recognised as the ‘gold standard’ to estimate the causal effects of clinical interventions (Goldfried and Wolfe, 1998; Shadish, Cook and Campbell, 2002). Considering the anticipated outcomes of medical interventions, for example objectively measurable blood pressure after therapy or improvement of symptoms after surgery, the choice of quantitative pre-defined outcome measures is appropriate.

Besides the current shift in the NHS towards the biopsychosocial model, experimental methods based on pre-defined quantitative outcomes are still considered to be the gold standard for producing robust evidence (Marchal *et al.*, 2013). However, the approach to evaluate clinical interventions, which is rooted in the biomedical model, may not be transferable to integrated care interventions based on the biopsychosocial model, such as SP. As SP addresses the wider determinants of health and shifts away from the view that biological indices are the ultimate criteria defining illness and poor wellbeing, the outcomes, consequently, go beyond the biomedical factors. Thus, reported service user outcomes such as ‘hope’, ‘happiness’, ‘increased self-confidence’, ‘improved social networks’, and ‘control over health and wellbeing’ (see section 8.3.2) fall under the psychosocial outcomes, which cannot be objectively measured with pre-defined quantitative outcome measures. Furthermore, the qualitative research on service user outcomes (see section 8.4.2) revealed that service user outcomes are interrelated. Service user 10, for example, reported that increased physical activity led to a healthier diet, reduced alcohol intake, improved mood, and increased self-confidence, which in turn led to better relationships with family members, improved mental wellbeing, and self-perception, which resulted in the confidence and interest to participate in local community activities. These complex relationships between reported service user outcomes, as well as the wider impact of SP on family members, carers, and communities cannot be captured with a single pre-defined quantitative outcome measure. Moreover, standardised health outcome measures may not be able to capture patients’ priorities, experiences, perspectives, as well as unanticipated and personal outcomes.

As indicated in the NHS Long Term Plan (NHS England, 2019b) and new GP contract (NHS England, 2019a), SP will be implemented on a national level in

England over the next five years. Parallel to the shift in policy and practice, a shift in research methods and perceived gold standards to evaluate the effectiveness of interventions based on the biopsychosocial model is required. Further work needs to be done to establish the right measurement methods, tools, and appropriate time scale for data collection. The current development of the Common Outcome Framework for SP (NHS England, 2018) is a first attempt to co-produce (with commissioners, practitioners, providers, evaluators, and other stakeholder groups) and test a wellbeing measure for SP, including a range of psychosocial outcomes, as well as the data collection methods and reporting of the wider determinants of health.

11.4.3 Transferability of findings

Critical realists see the world as an open system that is complex, various, and continuously changing. Therefore, they take the complexity of the ‘real world’ into account in which SP is implemented (see section 5.3 for a detailed description of critical realism). Moreover, critical realists believe that observable phenomena, human actions, and behaviours are embedded in a wide range of mechanisms, social processes, and structures (Bertotti *et al.*, 2017). Thus, for critical realists, the involvement of contextual factors in knowledge generation is key (Zachariadis, Scott and Barrett, 2013). In line with this assumption, the findings of this study showed that contextual factors, the delivery model, and involved stakeholders have influenced the implementation and delivery of the Luton SP pilot, and ability of mechanisms to produce changes in outcomes. Thus, not all factors affecting the implementation of the Luton SP pilot may be relevant for- and transferable to- other settings. However, as key principles and challenges are shared across SP programmes in primary care, findings can provide valuable information and guidance for policy makers, commissioners, and providers planning to implement, or up-scale, SP within primary care. The insights from the implementation research can also support SP’s planned transition from pilot work to sustainable primary care practice on a national level (NHS England, 2019b).

Due to the identified influence of contextual factors (e.g. the availability and accessibility of services) and mechanisms to produce change (e.g. trust in GPs, provider-service user relationships) in service user outcomes, it is unlikely that service user outcomes of complex and diverse interventions, such as SP, can be generalised across settings, populations, and time. However, the observed data patterns and associations identified in this study can inform policy and practice about the potential of SP to activate physically inactive groups and increase energy expenditure post-intervention. In addition, the identified mechanisms that

produced change can help practitioners, managers, and researchers to understand why and how SP programmes may work and observed outcomes have happened (Bertotti *et al.*, 2017).

11.5 Contribution to the field

This thesis makes theoretical, methodological, and policy related contributions to the field.

11.5.1 Theoretically

- This is the first study to use the RMIC to theoretically underpin a SP intervention. Thus, this study extends the use of the theory to a new type of intervention and context. The RMIC indicates that SP is dependent on clinical, professional, organisational, system, normative, and functional integration (the integration levels are discussed in detail in Chapter 4). This study suggests that there are challenges at all levels that need to be addressed before SP could be successfully implemented and delivered to achieve positive outcomes. In addition, this study contributes to the emerging, but yet weak, literature aiming to conceptualise SP.

11.5.2 Methodologically

- This thesis contributes to the knowledge base of the application of critical realism in ‘real world’ research. Besides the increasing academic interest and discussion about critical realism as a philosophical perspective, its practical application in research is less discussed. In this study, critical realism underpinned the research process from the development of the study design, through the data analysis, to the interpretation of the data.
- A mixed methods research design based on the critical realist stance provided information on the outcomes of SP programmes (i.e. success and failure), as well as insights on factors influencing observed outcomes. This methodology provided a comprehensive approach that enabled the development of an understanding of the processes that might produce or trigger observed outcomes.
- Interviewing various stakeholder groups and service users across engagement levels provided in-depth and comprehensive information from multiple stakeholder perspectives.

- This study has identified a discrepancy between the results of qualitative and quantitative studies on service user outcomes in the SP literature. In addition, possible explanations for the observed discrepancy were discussed.

11.5.3 Policy and planning

- This is one of the first studies to explore the barriers and facilitators to the implementation, factors affecting patient uptake and adherence, and service user outcomes of SP interventions. Given the momentum of SP, this process and outcome evaluation makes a valuable contribution to the policy, planning, implementation, and delivery of SP services.
- Specifically identifying facilitators and barriers to the implementation of SP holistic programmes allows decision-makers, managers, and practitioners to promote facilitators and overcome potential barriers, to improve the future implementation and up-scaling of SP interventions.
- This study provides an initial understanding of factors affecting the uptake and adherence to SP, enabling the refinement of programmes to enhance uptake and adherence, reduce health inequalities, and optimise investment.
- Findings of this study were continuously fed back and discussed with decision-makers, managers, the steering group, and navigators involved in the Luton SP programme. Research findings were regularly shared through written reports, face-to-face meetings, and presentations. This allowed regular reflection on the implementation process and delivery of the Luton SP programme and fast response to identified problems and challenges.

11.6 Recommendations

Based on the findings of this study, recommendations for policy and practice, research, and education can be made.

11.6.1 For policy and practice

- The selection of the first pilot surgeries in the Luton SP programme was based on staff's enthusiasm and willingness to participate in SP, rather than the available resources and capacities to implement and deliver SP. This led to delays in preparing

the surgery for the pilot (i.e. 'Navigator-ready surgeries') and long-term barriers to implementation due to, for example, the lack of available and suitable rooms for navigators and access to SystemOne in surgeries.

Recommendation: Surgeries should be selected based on their capacities and resources to implement SP, as well as their enthusiasm and interest in the service. To ensure that the required resources, capacities, and expectations are clear from the outset, a checklist could be used for every potential surgery, indicating the areas that require further work or could turn into potential barriers. Given that negotiations and discussions with GPs took longer than originally anticipated, enough time should be allowed to recruit and set up surgeries and to build relationships between partners. A phased-roll out approach to implementation may support the timely implementation of SP and facilitate cross-organisational and multidisciplinary working.

- Lack of shared understanding of the roles and responsibilities of stakeholders, expectations of providers and managers, communication pathways, the aims and scope of the SP programme, and the evaluation framework were identified as major barriers to implementation.

Recommendation: Clear and detailed job descriptions should be developed for all positions, outlining the roles of individuals, their responsibilities and what is expected from them in a given timeframe. If navigators are expected to collect data for the evaluation, data collection and reporting should be part of their job description. Failure to include evaluation related work in navigator's job description have lead to frustration in the Luton programme, as navigators perceived data collection and reporting as additional work, on top of their job roles. In addition, service level and partnership agreements should be signed by all stakeholders to ensure effective partnership working and shared understanding and knowledge about the programme.

- This study identified that primary care patients may refuse to be referred to a SP programme because they expect a medical solution to their problems.

Recommendation: The concept of integrated care and the consideration of psychosocial determinants of health should be promoted and discussed on a patient-level. It is important to ensure that the current shift towards the biopsychosocial model is not only happening at a policy, practice, and research level, but involves patients, who are the intended end users of the services.

- Free services seemed to promote the uptake of SP, but financial constraints to continue activities beyond the SP service hindered long-term outcomes.

Recommendation: Navigators should ensure, if appropriate, that service users can afford and are able to continue activities beyond the SP service before processing onward referrals.

11.6.2 For research

- This study identified a knowledge gap on the prevalence and reasons for inappropriate referrals from GPs to SP programmes. Additionally, it remains unclear how navigators should deal with ‘inappropriate referrals’. This study found that inappropriate referrals increased the workload of navigators and costs of the programme.

Recommendation: More research is required to understand the frequency, reasons, and consequences of inappropriate referrals to SP. In addition processes of how to deal with inappropriate referrals should be developed, to support navigators and ensure that they are working within their job roles and the scope of the SP programme.

- Patients who refused to be referred to SP could not be identified, and hence included in this study. Due to limited resources, only service users with sufficient English speaking skills were eligible for this study.

Recommendation: Future studies should include patients who refused a referral to SP to better understand the reasons for non-uptake and to improve the communication with this patient group. Understanding reasons for non-uptake is particularly important to prevent health inequalities, as those patients who refused to be referred may have the greatest need. Thus, it is recommended to collect data on the socio-demographic characteristics of patients who refuse uptake too, to assess patterns in the data. In order to understand the perspectives and experiences of non-English speaking service users, i.e. when translators were required or service users were referred to non-English speaking services, this group should be included in future research.

- Fear of stigma was found to hinder the uptake of SP (from a GP perspective).

Recommendation: Explore how fear of stigma associated with psychosocial problems affects the uptake and acceptance of SP services from a patient perspective.

- This quantitative study is one of the first to consider covariates (age, gender, working status) in relation to service user outcomes of SP. Trends became evident in the secondary data, demonstrating, for example, that the expected increase in energy expenditure is lower for older people and those working. Moreover, mental wellbeing improvements were greater for men (compared to women), not working service users (compared to working), and service user in the age group 64-73 years.

Recommendation: Future research should analyse service user outcomes by age, gender, working status, ethnicity, and other relevant service user characteristics, to compare outcomes between different groups.

- The systematic literature review found that the evidence base on SP is limited by poorly reported methodologies and results and the use of none validated measurement tools. In line with existing quantitative studies on SP, this quantitative study is limited by a high loss of follow-up and incomplete data. Given the lack of a shared IT system, not all secondary data were reported in a standardised way. This lead to the exclusion of data for the analysis in this study. During this mixed methods study, several barriers to robust evaluations were identified.

Recommendation: To strengthen the evidence base on SP, researchers should consider the following factors before starting data collection:

1. Clear objectives of the SP programme (and for quantitative research measureable outcomes) from the outset
2. Clear communication and agreements about roles and responsibilities in the evaluation process (recruitment of participants, data collection, reporting, management/storage, and analysis)
3. Set time periods for data collection and data analysis (e.g. for production of mid-term reports, final reports)
4. The selection of relevant and validated quantitative measurement tools from the outset
5. Training for individuals responsible for data collection and reporting
6. A shared IT system across front-line providers, to support the collection of standardised and complete data, needs to be in place. This study found that the development of shared IT systems took longer than anticipated due to leadership, information governance, and patient confidentiality issues.
7. Existing plans to ensure continuous data collection and recruitment of participants for research, in the case of staff turnover

8. Continuous monitoring and regular discussions of data collection, reporting, and the recruitment of participants

- Most analyses assess outcomes of SP at the short-term and lack a control group. Additionally, to date, little is known about the cost-effectiveness of SP. This study found that a weak evidence base on SP aggravated GPs' uptake and engagement in SP.

Recommendation: Robust mixed methods evaluations that follow participants on a long-term and include control groups are needed to assess and compare the outcomes of SP schemes. In addition, cost-effectiveness analyses need to be conducted to compare the cost-effectiveness of SP programmes with 'usual' care. Scientifically rigorous research on understanding the psychosocial context of health and its interplay with biological factors should be published in academic journals commonly accessed by clinicians.

- Although voluntary, community, and social enterprise (VCSE) organisations are a key part of SP services, SP related research in the UK focuses on service user outcomes and the impact on the health care system. In the available research on VCSE organisations in the context of SP, the different, i.e. voluntary, community, and social enterprise, organisations are often referred to 'community resources' as one. However, consistent with the findings of previous studies (Bertotti *et al.*, 2017), this study found that different types of organisations (e.g. voluntary and community) and sizes (e.g. small, medium, large) experience different challenges in the accreditation, implementation, and delivery of SP services. Interviews with stakeholders in voluntary sector organisations revealed that significant barriers for small and medium size organisations were the existing high demand for their services, already long waiting lists, and lack of funding to deliver additional services to SP service users (Bertotti *et al.*, 2017). This study also found that new and smaller community organisations struggle to complete the accreditation process, which on the other hand was perceived less challenging by bigger, well-established community organisations. These preliminary findings highlight that SP creates different challenges and opportunities for VCSE organisations of different sizes. Therefore, referring to- and treating all these different organisations as 'community resources' in research, is likely to be a simplification and hinders the development of a deeper understanding of opportunities and challenges for different VCSE organisations in the context of SP. To date, filtered analyses, by types and sizes of VCSE organisations, in the context of SP are missing.

Recommendation: More research is required on the challenges, opportunities, and experiences of VCSE organisations in the context of SP. It is important to analyse each type and size of organisations separately in the context of SP, to understand the specific challenges and opportunities, and adjust accreditation systems, implementation, and delivery processes accordingly. The Common Outcome Framework for SP (NHS England, 2018) is a good attempt to analyse the impact of SP on VCSE organisations, in addition to service user and system related outcomes. However, it is important that specific characteristics of the organisations are collected in the planned survey, to allow data filtering (by type, size of organisations) in the data analysis.

11.6.3 For education

- This study found that changes are required in the primary care culture towards the biopsychosocial model of care and in health professionals' behaviour and perspectives in order to implement SP successfully. It became apparent that the medical education and training of GPs is based on the biomedical model of care and that SP was perceived as a 'new concept' outside of GPs' routine practice.

Recommendation: The curricula of medical education should be reviewed to incorporate the wider determinants of health and strengthen the biopsychosocial approach to healthcare. Understanding the role of wider determinants of health as medical students may help the future generation of health professionals to incorporate the social, psychological, and behavioural dimensions of illness into clinical practice to improve care and outcomes. Seeing the biopsychosocial story of patients, rather than giving primacy to biological factors alone, is a key element of integrated care. Initiatives such as the 'National Social Prescribing Student Champion Scheme' (Giurca, 2018) should be further promoted, to enable today's medical students to learn, teach, and promote SP in their region and to explore the need to formally introduce concepts such as SP within the undergraduate medical school curriculum.

12 Appendices

Appendix 1: Search strategy used to search electronic databases

The advanced search techniques were adjusted to meet the different requirements of the included electronic databases.

Box 1. Demonstrating search strategy for CINAHL (EBSCOhost)

Search 1

social N1 prescri* OR community N1 prescri* OR “community referral” OR “community referrals” OR “social referral” OR “social referrals” OR “social intervention” OR “social interventions” OR “linking scheme” OR “linking schemes” OR exercise N2 prescription OR books N2 prescription OR arts N2 prescription OR prescription N2 learning OR education N2 prescription

Search 2

“primary care” OR “primary-care” OR “health care” OR healthcare OR “health-care” OR “general practice” OR “PCT” OR “National Health Service” OR “NHS” OR “health centres” OR “health centre” OR “health services” OR “health service” OR “social care”

Search 3

UK OR “United Kingdom” OR England OR “Northern Ireland” OR Scotland OR Wales OR “Great Britain”

Search 4

Health OR wellbeing OR “well-being”

Search 5

Search 1 AND Search 2 AND Search 3 AND Search 4

The NX operator indicates within X words

* Indicates truncation to find all forms of that word

“” Indicates that the search engine looks for words in the exact order

Appendix 2: Quantitative outcome measures to measure service user outcomes and reported results

Table 33: Quantitative outcome measures used in included studies to measure service user outcomes and reported results

	Number of studies, authors, and date	Quantitative outcome measures	Reported results
	Mental health and wellbeing		
	1. ERS Research and Consultancy, 2013 2. Wigfield <i>et al.</i> , 2015	7-item Warwick Edinburgh Mental Wellbeing Scale (WEMWBS)	1. Trend reported: Improvement in mental wellbeing 2. No statistically significant difference: $p=0.359$
	1. Friedli <i>et al.</i> , 2012 2. Brandling <i>et al.</i> , 2011 3. Age UK, n.d 4. Vogelpoel and Jarrold, 2014 5. Baines, 2015	14-item WEMWBS	1. Statistically significant improvement in WEMWBS scores. $P<0.05$ 2/3/4/5. Positive trend reported: Improvement in perceived wellbeing
	1. The Health Foundation, 2015 2. Grant <i>et al.</i> , 2000	Hospital Anxiety and Depression scale (HADS)	1. No statistically significant change for depression ($p=0.29$) and anxiety ($p=0.90$) 2. Statistically significant greater improvement in anxiety ($p=0.002$) in intervention than control group, no statistically significant change in depression ($p=0.116$) between intervention and control group
	1. Kimberlee, 2014	Patient Health Questionnaire 9 (PHQ9) Scale for depression	1. Statistically significant improvement: $p<0.001$
	1. Kimberlee, 2014	Generalised Anxiety Disorder - 7 (GAD7)	1. Statistically significant improvement: $p<0.001$
	1. Grayer <i>et al.</i> , 2008	Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM)	1. Statistically significant change: Difference=2.7, 95% CI=1.2-4.2
	General health and wellbeing (including physical health)		
	1. Grayer <i>et al.</i> , 2008	General Health Questionnaire 12 (GHQ-12)	1. Statistically significant change: Difference=2.38, 95% CI=1.25-3.51
	1. The Health Foundation, 2015	General Health Score (Tool not specified)	1. No statistically significant change: $p=0.47$
	1. The Health Foundation, 2015	General Wellbeing Scale (Tool not specified)	1. No statistically significant change: $p=0.97$
	1. Brandling <i>et al.</i> , 2011	Adopted Measure Yourself Medical Outcome Profile 2 (MYMOP2)	1. Trend reported: Improvement in general health and wellbeing

Table 33 continued	Number of studies, authors, and date	Quantitative outcome measures	Reported results
	1. Kimberlee, 2014	Office for National Statistics (ONS) Wellbeing Scale (four indicators: satisfaction with life, feeling happy, feeling anxious, feeling doing worthwhile things in life)	1. All of the four wellbeing indicators found a statistically significant improvement: $p<0.05$
	1. Grant <i>et al.</i> , 2000	COOP/WONCA functional health assessment charts	1. The intervention group showed a statistically significant greater improvement in pain, feelings, daily activities, change in health, and change in overall health, than the control group: $p<0.05$
	1. Grant <i>et al.</i> , 2000	Delighted-Terrible Faces Scale (Quality of life)	1. The intervention group showed a statistically significant greater improvement on the Delighted-Terrible Faces scale, than the control group: $p<0.05$
	1. Dayson <i>et al.</i> , 2016	Rotherham wellbeing scale (Consists of eight measures associated with aspects of self-management: Feeling positive, lifestyle, looking after yourself, managing symptoms, work, volunteering and other activities, money, where you live, and family and friends. For each measure a five point scale was used 1: Not thinking about it to 5: As good as it can be)	1. 82% (N=876) of service users experienced positive change on at least one outcome measure at follow-up (3-4 months) compared to baseline scores
	1. Farenden <i>et al.</i> , 2015	Questions to measure enhanced wellbeing and quality of life (Indicators: Reduced isolation, increased social activity, community links, improvement in wellbeing)	1. 84% (N=84) of the interviewed service users experienced improvements in their sense of wellbeing 3-6 months after completing the SP programme
	1. Carnes <i>et al.</i> , 2017 2. Loftus <i>et al.</i> , 2017	Medication prescription	1. No statistically significant change: $p=0.156$ 2. 1. No statistically significant change: $p=0.084$
	Health related behaviours		
	1. Wigfield <i>et al.</i> , 2015	Question about attitudes to healthy eating	1. No statistically significant change: $p=0.164$
	1. Wigfield <i>et al.</i> , 2015	Question about fruit and vegetables consumption	1. No statistically significant change: $p=0.175$

Table 33 continued	Number of studies, authors, and date	Quantitative outcome measures	Reported results
	1. Wigfield <i>et al.</i> , 2015	Question about attitude to physical activity	1. Statistically significant change reported constantly in text but presented $p=0.10$
	1. Wigfield <i>et al.</i> , 2015	Questions about minutes walking per week and hard breathing activities	1. Statistically significant improvement for minutes walking per week ($p=0.40$), statistically significant increase in hard breathing exercise constantly reported in text but p-value reported as $p=>0.01$
	1. Kimberlee, 2014	International Physical Activity Questionnaire (IPAQ)	1. Statistically significant improvement: $p<0.001$
	Self-confidence		
	1. ERS Research and Consultancy, 2013	Confidence scale (Unspecified tool)	1. Trend reported: Increase in confidence
	Daily functioning		
	1. Friedli <i>et al.</i> , 2012 2. Grayer <i>et al.</i> , 2008	Work and Social Adjustment Scale (WSAS)	1. Statistically significant change: $p<0.05$ 2. Statistically significant change: Difference=3.69, 95% CI=1.54-5.84
	1. The Health Foundation, 2015	Positive and active engagement in life (Unspecified tool)	1. No statistically significant change: $p=0.90$
	Social interactions		
	1. Grant <i>et al.</i> , 2000	Duke-UNC functional social support questionnaire	1. No statistically significant change in the intervention group compared to the control group: Confidant support $p=0.221$ and affective support $p=0.594$
	1. Kimberlee, 2014	Friendship Scale for Isolation	1. Statistically significant improvement: $p<0.001$
	1. Wigfield, 2015	Four indicators (companionship, feeling isolated, left out, in tune with others around) to measure social isolation and loneliness (no specified tool)	1. None of the four indicators found a statistically significant change: $p>0.05$

Appendix 3: Quality appraisal for each included study by the criteria of the Mixed Methods Appraisal Tool (MMAT) Version 2011

Table 34: Results of the Mixed Methods Appraisal Tool (MMAT) used for the quality appraisal of included studies

	Screening questions			Qualitative		
Authors and date of publication	Are there clear qualitative, quantitative, or mixed methods research questions (objectives)?	Do the collected data allow address the research questions (objectives)?	Are the sources of qualitative data relevant to address the research question (objective)?	Is the process for analysing qualitative data relevant to address the research question (objective)?	Is appropriate consideration given to how findings relate to the context?	Is appropriate consideration given to how findings relate to the researcher's influence?
Brandling <i>et al.</i> , 2011	Yes	Yes	Yes	Yes	Yes	No
Dayson <i>et al.</i> , 2016	Yes	Yes	Yes	Can't tell	Yes	No
ERS Research and Consultancy, 2013	Yes	Yes	Yes	Can't tell	Yes	No
The Health Foundation, 2015	Yes	Yes	Yes	Can't tell	Yes	No
Age UK, n.d	No	Can't tell	Can't tell	Can't tell	No	No
Friedli <i>et al.</i> , 2012	Yes	Yes	Yes	Can't tell	Yes	No
Farenden <i>et al.</i> , 2015	Yes	Yes	Yes	Can't tell	Yes	No
Grant <i>et al.</i> , 2000	Yes	Yes	Na	Na	Na	Na
Grayer <i>et al.</i> , 2008	Yes	Yes	Na	Na	Na	Na
Vogelpoel and Jarrold, 2014	Yes	Yes	Yes	No	Yes	No
Loftus <i>et al.</i> , 2017	Yes	Yes	Na	Na	Na	Na
Skivington <i>et al.</i> , 2018	Yes	Yes	Yes	Yes	Yes	No
Whitelaw <i>et al.</i> , 2017	Yes	Yes	Yes	Yes	Yes	No
Carnes <i>et al.</i> , 2017	Yes	Yes	Yes	Yes	Yes	No
Moffat <i>et al.</i> , 2017	Yes	Yes	Yes	Yes	No	No
Baines, 2015	Yes	Yes	Yes	Can't tell	No	No
Kimberlee <i>et al.</i> , 2014	Yes	Yes	Yes	Can't tell	Yes	No
White, 2010	Yes	Yes	Yes	Yes	No	No
Wigfield <i>et al.</i> , 2015	Yes	Yes	Yes	Yes	No	No

Table 34 continued

	Quantitative randomized controlled (trials)				Quantitative non-randomized			
Authors and date of publication	Is there a clear description of the randomization (or sequence generation)?	Is there a clear description of the allocation concealment (or blinding when applicable)?	Are there complete outcome data (80% or above)?	Is there low withdrawal/ dropout (below 20%)?	Are participants (organisations) recruited in a way that minimises selection bias?	Are measurements appropriate regarding the exposure/ intervention and outcomes?	In the group being compared, are the participants comparable, or do researchers take into account the differences between groups?	Are their complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or follow-up rate for cohort studies?
Brandling <i>et al.</i> , 2011	Na	Na	Na	Na	Na	Na	Na	Na
Dayson <i>et al.</i> , 2016	Na	Na	Na	Na	Na	Na	Na	Na
ERS Research and Consultancy, 2013	Na	Na	Na	Na	Na	Na	Na	Na
The Health Foundation, 2015	Na	Na	Na	Na	Can't tell	Yes and can't tell**	Yes	No, with one exception***
Age UK, n.d	Na	Na	Na	Na	Na	Na	Na	Na
Friedli <i>et al.</i> , 2012	Na	Na	Na	Na	Na	Na	Na	Na
Farenden <i>et al.</i> , 2015	Na	Na	Na	Na	Na	Na	Na	Na
Grant <i>et al.</i> , 2000	Yes	Yes	Yes	No	Na	Na	Na	Na
Grayer <i>et al.</i> , 2008	Na	Na	Na	Na	Na	Na	Na	Na
Vogelpoel and Jarrold, 2014	Na	Na	Na	Na	Na	Na	Na	Na
Loftus <i>et al.</i> , (2017)	Na	Na	Na	Na	Na	Na	Na	Na
Skivington <i>et al.</i> , 2018	Na	Na	Na	Na	Na	Na	Na	Na
Whitelaw <i>et al.</i> , 2017	Na	Na	Na	Na	Na	Na	Na	Na
Carnes <i>et al.</i> , 2017	Na	Na	Na	Na	Na	Na	Na	Na
Moffat <i>et al.</i> , 2017	Na	Na	Na	Na	Na	Na	Na	Na
Baines, 2015	Na	Na	Na	Na	Na	Na	Na	Na
Kimberlee <i>et al.</i> , 2014	Na	Na	Na	Na	Na	Na	Na	Na
White, 2010	Na	Na	Na	Na	Na	Na	Na	Na
Wigfield <i>et al.</i> , 2015	Na	Na	Na	Na	Na	Na	Na	Na

Table 34 continued

Authors and date of publication	Quantitative descriptive				Mixed methods		
	Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods research question)?	Is the sampling representative of the population under study?	Are measurements appropriate?	Is there an acceptable response rate (60% or above)?	Is the mixed methods research design relevant to address the qualitative and quantitative research questions (objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?	Is the integration of qualitative and quantitative data (or results) relevant to address the research question (objectives)?	Is appropriate consideration given to the limitations associated with this integration in a triangulation design?
Brandling <i>et al.</i> , 2011	Yes	Yes	Yes	Can't tell	Yes	Yes	No
Dayson <i>et al.</i> , 2016	Yes	Yes	No	Yes	Yes	Yes	No
ERS Research and Consultancy, 2013	Yes	No	One Yes one No	Can't tell	Can't tell	Can't tell	No
The Health Foundation, 2015	Na	Na	Na	Na	Yes	Can't tell	No
Age UK, n.d	Can't tell	Can't tell	Yes	Can't tell	Can't tell	Can't tell	No
Friedli <i>et al.</i> , 2012	Can't tell	No	Yes	Can't tell	Yes	Can't tell	No
Farenden <i>et al.</i> , 2015	Yes	Yes	Can't tell	No	Yes	Yes	No
Grant <i>et al.</i> , 2000	Na	Na	Na	Na	Na	Na	Na
Grayer <i>et al.</i> , 2008	Yes	No	Yes	Yes	Na	Na	Na
Vogelpoel and Jarrold, 2014	Yes	No	Yes	Yes	Yes	Yes	No
Loftus <i>et al.</i> , 2017	Yes	No	Yes	No	Na	Na	Na
Skivington <i>et al.</i> , 2018	Na	Na	NA	Na	Na	Na	Na
Whitelaw <i>et al.</i> , 2017	Na	Na	Na	Na	Na	Na	Na
Carnes <i>et al.</i> , 2017	Yes	Yes	Yes	No	Yes	Yes	No
Moffat <i>et al.</i> , 2017	Na	Na	Na	Na	Na	Na	Na
Baines, 2015	Yes	No	Yes	No	Yes	Yes	No
Kimberlee <i>et al.</i> , 2014	Yes	Yes	Yes	Yes	Yes	Yes	No
White, 2010	Na	Na	Na	Na	Na	Na	Na
Wigfield <i>et al.</i> , 2015	Yes	Yes	No	No	Yes	Yes	No

INVITATION LETTER

Research study: Facilitators and barriers to the implementation and delivery of Social Prescribing services

Dear [name],

I would like to invite you to take part in a research study. I hold a master degree in Public Health and I am undertaking further study at University of Bedfordshire towards a PhD degree. I am conducting research to explore factors that hinder and facilitate the implementation and delivery of Social Prescribing services. As you are involved in the [implementation and/or delivery] of the SP service in Luton, your views and experiences would provide me with valuable information about [the implementation and delivery] of the Luton Social Prescribing service.

[*Addition to the letter for GPs only:* It does not matter if you referred patients to Social Prescribing often or not. I would like to hear why GPs do and do not refer their patients to the service.]

I would be grateful if you would take time to read the information sheet that is attached to this email. Please fill in the attached contact form and return it to me via email by the [date]. Taking part is entirely voluntary therefore, if you do not wish to do so, this will not affect you in anyway. Any information you give will be treated in the strictest confidence and will be anonymised.

If you have any questions, I can be contacted via phone at 07542411423 or via email at julia.pescheny@study.beds.ac.uk.

I hope you will be willing to help me by agreeing to take part.

Yours sincerely,
Julia Pescheny



INFORMATION SHEET

VERSION 2G1

Research study: Facilitators and barriers to the implementation and delivery of Social Prescribing services

I would like to invite you to take part in a research study. Before you decide it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

- Part 1 tells you about the purpose of this study and gives you more detailed information about taking part
- Part 2 provides you information about the conduct of the study
- Part 3 tells you what to do and what will happen if you decide to take part

If there is anything that is not clear or if you would like more information, please feel free to contact me (Tel: 07542411423 or at julia.pescheny@study.beds.ac.uk). Please take time to decide whether or not you wish to take part. Participation is entirely voluntary.

Part 1:

What is the purpose of the study?

Social Prescribing is a quite new service in general practice. The research study aims to explore factors that facilitate and hinder the implementation and delivery of Social Prescribing services. Findings may help to develop our understanding of how to improve the implementation and delivery of Social Prescribing services in the future. This research is part of the researcher's studies at University of Bedfordshire.

Why have I been asked to take part?

You have been invited to take part in this study because you are involved in the implementation and/or delivery of the Social Prescribing service in Luton.

Do I have to take part?

No. Taking part is entirely voluntary and does not affect you in any way. You can opt out of the research study at any time without providing any reason.

Will my taking part in the study be kept confidential?

Yes. All information about you taking part in the study will be kept confidential.

What would be involved?

I would like to discuss your views and experiences of the implementation and delivery of the Social Prescribing service in Luton in a face-to-face interview, which should take about 30-40 minutes. The interview will be conducted at a place, day, and time convenient for you. In order to remember everything you tell me, the interview will be audio recorded.

What if I have any questions or want more information before I decide whether to take part?

Please do not hesitate to contact me – Julia Pescheny. You can either call me on 07542411423 or email me at julia.pescheny@study.beds.ac.uk.

What are the possible benefits of taking part?

Although you may not benefit personally from taking part in this study, the information you give may help to improve the implementation and delivery of Social prescribing services in the future.

Part 2:**Confidentiality**

All information collected during the course of this research will be kept confidential and stored in line with the Data Protection Act 1998.

What will happen with the information I gave in the interview?

From the audio recording of the interview, I will type your answers as you said them into a computer database. Any information that can identify you, for example names or organisations, will not be typed. Things you said may be quoted in the final results but any identifiable information will have been removed. The audio recording will be destroyed at the end of the research.

What will happen to the results of this study?

The results of this study will form the basis of my PhD thesis, due for completion by October 2018. It is planned that articles based on the findings of this research will be published in professional journals. Furthermore, they may be reported to the Social Prescribing team and the Luton Borough Council to learn and improve the service. When we meet, I will ask you if you wish a summary of the findings to be sent to you.

Complaints

If you are unhappy or have any concerns about this research study you can contact me on 07542411423 or at julia.pescheny@study.beds.ac.uk. If you wish to make a formal complain, you can do this through my supervisor, Dr. Yannis Pappas. He can be contacted at Yannis.Pappas@beds.ac.uk or 07742522603.

Who have reviewed this study?

To protect participants' safety, rights, wellbeing and dignity, this research has been reviewed by the Institute for Health Research Ethics Committee at the University of Bedfordshire. This study has been reviewed and given favourable opinion by the 17th of November 2016.

Part 3:**What to do if I decide to take part?**

Please make sure you have read Part 1 and Part 2 of the information sheet carefully and understand the purpose of the study, what will happen with the information you give, your rights, and the voluntary nature of taking part. If you agree to take part, please complete the provided contact form and return it to me via email.

What will happen after I returned the contact form?

After I receive your reply, I will contact you to arrange a suitable day, time, and place in Luton to meet for the interview. The interview will take about 30-40 minutes and will be audio recorded. Before we start with the interview, I will ask you to read and sign a consent form, which states that you have agreed to take part in this study.

Thank you for taking time to read this sheet.



CONTACT FORM
VERSION 2F2

Research study: Facilitators and barriers to the implementation and delivery of Social Prescribing services

Please fill in the form and return it to me by [Date].

Name:

Organisation/Role:.....

I do not agree to take part in the research study

☐

I agree to take part in the research study

☐

Preferred method of contact:

E-mail

☐

Other

☐

.....

Thank you very much for returning this form.

Yours sincerely,
Julia Pescheny



Title of the research study: Social Prescribing: Engagement and outcomes for service users

Dear Sir or Madame,

I am writing to you to ask for your help. I would like to invite you to take part in a research study. I hold a master degree in Public Health and I am undertaking further study at University of Bedfordshire towards a PhD degree. I am conducting research to explore factors that affect engagement with Social Prescribing and perceived outcomes of participating in the service. It does not matter if you did or did not engage with the Social Prescribing service. I would like to hear from people who do not use the service and their experiences, as well as from those that do. Your views and experiences would provide me with valuable information about service user engagement and service outcomes.

I would be grateful if you would take time to read the information sheet you have been given. If you wish to take part, please fill out the enclosed contact sheet and return it to me in the freepost envelope provided. Alternatively, you can bring the envelope with the enclosed contact sheet to the general practice reception, where I will pick it up. Please return the sheet within two weeks. The Social Prescribing team forwarded this letter to you on my behalf, so I will not contact you again unless you reply to me.

This research study is independent from the general practice. Taking part is entirely voluntary and if you do not wish to do so, this will not affect your care in any way. Any information you give will be treated with the strictest confidence and will be anonymised. If you have any questions, please do contact me. I can be contacted via phone at 07542411423 or via email at julia.pescheny@study.beds.ac.uk.

Thank you for taking time to read this letter. I hope you will be willing to help me by agreeing to take part.

Yours sincerely,
Julia Pescheny



INFORMATION SHEET

Version 3E1 17.01.2017

Title of the research study: Social Prescribing: Engagement and outcomes for service users

IRAS ID: 209616

I would like to invite you to take part in a research study. Before you decide, it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

- Part 1 tells you about the purpose of this study and gives you more detailed information about taking part
- Part 2 provides you with information about the conduct of the study
- Part 3 tells you what to do and what will happen if you decide to take part

If there is anything that is not clear or if you would like more information, please feel free to contact me (Tel: 07542411423 or at julia.pescheny@study.beds.ac.uk). Please take time to decide whether or not you wish to take part. Participation is entirely voluntary.

Part 1:

1. What is the purpose of the study?

Social Prescribing is a quite new service in general practice. The research study aims to explore factors that affect service user engagement in Social Prescription and the outcomes of the service. This research is part of the researcher's studies at University of Bedfordshire towards a PhD degree.

2. Why have I been asked to take part and who send me this letter?

You have been invited to take part in this study because your family doctor referred you to the Social Prescribing service some time over the past year. It does not matter whether you engaged with the service or not, your views and experiences are of special interest to me. The

Social Prescribing team sent this letter to you on my behalf. Your privacy is fully protected and I will not contact you again if you do not reply to me.

3. Do I have to take part?

No. Taking part is entirely voluntary and does not affect the care and service you receive from your family doctor or Social Prescribing service. You can opt out of the study at any time without providing any reason.

4. Will my taking part in the study be kept confidential?

Yes. All information about you taking part in the study will be kept confidential.

5. What would be involved?

I would like to discuss your views and experiences with the service in an interview, which should take about one hour. The interview will be conducted in Luton at a place, day, and time convenient for you. In order to remember everything you tell me, the interview will be audio-recorded.

6. What if I have any questions or want more information before I decide whether to take part?

Please do not hesitate to contact me – Julia Pescheny. You can either call me on 07542411423 or email julia.pescheny@study.beds.ac.uk.

7. What are the possible benefits of taking part?

Although you may not benefit personally from taking part in this study, the information you give may help to improve Social Prescribing programmes in the future.

Part 2:

8. Confidentiality

All information collected during the course of this research will be kept confidential and stored in line with the Data Protection Act 1998.

9. What will happen with the information I gave in the interview?

From the audio recording of the interview, I will type your answers as you said them into a computer database. Any information that can identify you, for example names or places, will not be typed. Things you said may be quoted in the final results but any identifiable information will be removed. The audio recording will be destroyed as soon as I typed your answers.

10. What will happen to the results of this study?

The results of this study will form the basis of my PhD thesis, due for completion by October 2018. It is planned that articles based on the findings of this research will be published in professional journals. They may also be reported to the Social Prescribing team and the Luton Borough Council to learn and improve the service. When we meet, I will ask you if you would like a summary of the findings to be sent to you. If yes, you can provide either your email address or postal address, which I will use to send the results to you. Your contact details will be stored in a secure place at University premises until I have sent you the results of the research study. It is planned that you receive a summary of the results by August 2017.

11. Complaints

If you are unhappy or have any concerns about this research study, you can contact me at julia.pescheny@study.beds.ac.uk or Tel: 07542411423. If you wish to make a formal complain, you can do this through my supervisor, Dr. Yannis Pappas. He can be contacted at Yannis.Pappas@beds.ac.uk or Tel: 07742522603.

12. Who has reviewed this study?

To protect participants' safety, rights, wellbeing and dignity, an independent group of people, called a Research Ethics Committee, review all research in the NHS. This study has been reviewed by the Research Ethics Committee and given favourable opinion by the 23rd of January 2017.

Part 3:

13. What to do if I decide to take part?

Please make sure you have read Part 1 and Part 2 of the information sheet carefully and understand the purpose of the study, what will happen with the information you give, your rights, and the voluntary nature of taking part. If you agree to take part, please complete the provided contact sheet and either:

1) Return it to me in the freepost envelope provided within two weeks. Returning the contact sheet in the provided envelope will not cost you anything.

Or

2) Return the envelope with the contact sheet to the reception at the general practice within two weeks, where I will pick it up.

If you have any questions about this process please feel free to contact me (Tel: 07542411423 or at julia.pescheny@study.beds.ac.uk).

14. What will happen after I returned the contact sheet?

After I receive your reply, I will contact you to arrange a suitable place, day, and time to meet for the interview. The interview will take about an hour. If we meet, I will ask you to read and sign a form, which states that you have agreed to take part in this study and read and understood this information sheet.

Thank you for taking time to read this sheet.



CONTACT FORM
Version 3C 01.11.2016

Title of the research study: Social Prescribing: Engagement and outcomes for service users

IRAS ID: 209616

Please print in block capitals

Surname:

First name:

Address:

Telephone number (landline):

Mobile number:

E-mail address:

Preferred method of contact

Telephone (landline)

☐

Mobile phone

☐

E-mail

☐

Other:

Preferred time to be contacted:

Day/s:

Time:

Please return this form to me in the addressed envelope provided or bring it to the general practice reception where I will pick it up.

Thank you!

GUIDANCE FOR NAVIGATORS – RECRUITMENT OF PATIENTS

1. ELIGIBILITY CRITERIA

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">• Referred to the SP service by a GP• Referred to SP some time over the past year (from the point on when recruitment of participants start in the study)• Sufficient English speaking skills to take part in the study	<ul style="list-style-type: none">• Service users with significant hearing impairments

- Basically, all patients that were referred over last year, have sufficient English skills, and no significant hearing impairments can be invited to the study
- Patients can be at all stages in the SP programme, they DO NOT need to be ‘completer finishers’, I am interested in those as well who did not engage, dropped out, or did not complete SP as intended

2. HANDING AND SENDING OUT RECRUITMENT PACKS

- Eligible patients can be identified through routine appointments or through scanning of the patient records.
- There are yellow envelopes, which can be send out to patients via post (Patient’s address can be written on the yellow envelope). Within the yellow envelope is the information material and a white pre-paid and addressed envelope, which patients can use to return the contact form to me. Alternatively they can bring the envelope back to the GP reception.

If recruitment packs are handed out in person:

- The recruitment packs are in white addressed envelopes, which can be handed out directly to patients. Patients should read the material in the envelope carefully, and if they wish to take part in the study, they should fill in the included contact form. Patients can use the white addressed envelope to send the contact form back to me

free of charge (please highlight when you explain this option that it is free for them to send the envelope back) or they can return it to GP reception.

3. IMPORTANT POINTS TO HIGHLIGHT

- The information in the recruitment pack should be read carefully before deciding whether to participate in the study
- Participation is voluntary
- Participants can opt out at any time without providing any reason
- The study is independent from the general practice and SP service and therefore their decision to take part will not affect the care they receive in any way
- If service users have any questions regarding the study they should contact the researcher (Contact details are provided in the recruitment pack)

CHECKLIST

- GP receptionists are informed about the study, collect, and store the returned envelopes for the researcher in a save place at reception

Appendix 11: Institute for Health Research Ethics Approval



16 November 2016

Julia Pescheny
Student number: 1516475

Dear Julia Pescheny

Re: IHREC Application No: IHREC691
Project Title: Facilitators and barriers to the implementation and delivery of Social Prescribing services

The Ethics Committee of the Institute for Health Research has considered your revised application and has decided that the proposed research project should be approved with no further amendments.

Please note that if it becomes necessary to make any substantive change to the research design, the sampling approach or the data collection methods a further application will be required.

A handwritten signature in black ink, appearing to read "Mike Cook", written over a horizontal line.

Yours sincerely

Professor Mike Cook
Institute for Health Research
On Behalf of the Institute for Health Research Ethics Committee



Miss Julia Vera Pescheny
PhD student
University of Bedfordshire, Luton Campus
University Square
Luton, Bedfordshire
LU1 3JU

Email: hra.approval@nhs.net

23 January 2017

Dear Miss Pescheny,

Letter of HRA Approval

Study title:	Social Prescribing: Engagement and outcomes for service users
IRAS project ID:	209616
Protocol number:	na
REC reference:	16/NE/0389
Sponsor	University of Bedfordshire

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **209616**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Yannis Pappas, University of Bedfordshire, (Sponsor Contact)*
Mr. Paul Lindars, Luton Clinical Commissioning Group (CCG),
(Lead NHS R&D Contact)

IRAS project ID	209616
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Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	Version	Date
Contract/Study Agreement [Student certificate]	1	06 June 2016
Covering letter on headed paper [Response email to queries]		21 November 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UMAL (Indemnity insurance)]	1	05 July 2016
Interview schedules or topic guides for participants [Interview schedule - Service user]	3A	09 November 2016
IRAS Application Form [IRAS_Form_11112016]		11 November 2016
IRAS Checklist XML [Checklist_11112016]		11 November 2016
Letters of invitation to participant [Invitation letter]	3F	01 November 2016
Other [HRA Statement of Activities]	1	23 January 2017
Other [IRAS ID 209616 Corrections]		
Other [Sponsor Letter]		17 January 2017
Other [HRA Schedule of Events]	1	23 January 2017
Participant consent form	3B1	17 January 2017
Participant information sheet (PIS)	3E1	17 January 2017
Referee's report or other scientific critique report [Progression Point 1 Form- First Viva]	1	22 June 2016
Research protocol or project proposal [Study protocol]	1	07 November 2016
Summary CV for Chief Investigator (CI) [CV-Julia Pescheny]	1	07 November 2016
Summary CV for student [CV-Julia Pescheny]	1	07 November 2016
Summary CV for supervisor (student research) [CV-Yannis Pappas]	1	07 January 2016



CONSENT FORM

Version 2E1

Research study: Facilitators and barriers to the implementation and delivery of Social Prescribing services

Researcher: Julia Pescheny

Name of interviewee:

Please initial each box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to think about the information, discuss, and clarify any points I did not understand.

☐

2. I understand that taking part is voluntary and that I am free to withdraw from the study at any time without giving any reason.

☐

3. I agree that my interview will be audio recorded and things I say may be quoted, for example in the PhD thesis, research reports, and published articles.

☐

4. I agree to take part in the above study.

☐

5. I wish/ do not wish to receive a summary of the findings via email/ post to:

.....
.....

Name of participant

Date

Signature

Name of person taking consent

Date

Signature



CONSENT FORM
Version 3B1 17.01.2017

Title of the research study: Social Prescribing: Engagement and outcomes for service users

IRAS ID: 209616

Participant ID:

Name of Researcher: Julia Vera Pescheny

Please initial each box

1. I confirm that I have read and understand the information sheet dated 17.01.2017 version 3E1 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐

2. I understand that taking part is voluntary and that I am free to withdraw from the study at any time, without giving any reason.

☐

3. I understand that taking part in the study will be confidential and will not affect the care, service, and support I receive from the general practice and Social Prescribing service.

☐

4. I agree that my interview will be audio recorded and things I say may be quoted, for example in the PhD thesis, research reports, and published articles.

☐

5. I agree to take part in the above study.

☐

6. I wish/ do not wish to receive a summary of the findings via email/ post to:

.....
.....

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

TOPIC GUIDE – GENERAL PRACTITIONER

Topic Guide version 2B1 29.11.2016

Name of interviewee:

General Practice:

Date of interview:

Obtaining consent

Thank you for agreeing to take part in this interview. The interview will take about 30-40 minutes. There are no right or wrong answers to my questions. I am interested in your views and experiences. You do not have to answer any question you do not want to. I will record the answers that you give me and the information that you provide will be used in my PhD thesis, reports, and journal articles. Any quotes and information will be anonymised and I will do all that I can to ensure that you cannot be identified in the write-ups. You will be referred to GP (number) when findings are written-up for the thesis, reports, and publications. Please remember that participation is voluntary and you may stop this interview at any time without giving any reason.

Before we start, I would like to ask you to sign two copies of the consent form – one for you to keep and one for my research file. Please take time to read the consent form and ask me any questions you might have before you initial each box and sign.

Defining terms

Social Prescribing is a relatively new service in Luton. You were one of the first general practitioners participating in this service. I would like to ask you questions about your role, views, and experiences of the Social Prescribing service in Luton. I am also interested in your views about patient engagement and outcomes for patients. Do you have any questions regarding these terms?

PART A IMPLEMENTATION AND DELIVERY

1. Social Prescribing

a. How would you describe the Social Prescribing service in Luton?

2. Involving health professionals

a. When and how did you hear about the Social Prescribing service in Luton?

b. Do you remember what you felt and thought when you heard about SP the first time?

c. Why did you decide to participate in the Social Prescribing service in Luton?

d. Do you know surgeries and health professionals who refused to participate in a Social Prescribing service?

(i) If yes, do you know why they refused to participate?

3. Implementation

Think about what happened after you agreed to participate in the Social Prescribing service in Luton.

a. From your experience, what helped, and what made it difficult to put Social Prescribing into practice in this surgery?

4. Delivery

a. Can you tell me about your role in the Social Prescribing service?

(i) What criteria do you use to identify patients for Social Prescribing?

(ii) Do you refer patients to the Social Prescribing service on a regular basis?

- Why?/ Why not?

(iii) How do you start a conversation about Social Prescribing?

(iv) Do you know what happens to patients once you have referred them to the Social Prescribing service?

- How does this affect you?

(v) With whom do you communicate regarding the delivery of the Social Prescribing service (e.g. navigators, practice managers, service providers in the third sector)?

b. Can you think of something that helps you to perform your role in the Social Prescribing service (identifying and referring patients)?

c. Do you face any challenges in performing your role in the Social Prescribing service?

(i) What are these challenges?

d. What would help you to overcome these challenges?

5. Final question

a. Is there anything else you would like to tell me about the implementation and delivery of the Social Prescribing service that I have not asked you about?

PART B ENGAGEMENT

6. Referrals

- a.** Can you tell me how patients react when you suggest Social Prescribing to them?
- b.** Do you know why patients agreed to be referred to the Social Prescribing service when you suggested it to them?
- c.** Did patients ever refuse to participate when you suggested Social Prescribing in a consultation?
 - (i)** *If yes*, do you know why patients refused to be referred to the Social Prescribing service?
- d.** Do you know if a referred patient did not meet with the navigator?
 - (i)** *If yes*, do you know why this happened?
- d.** Do you know why referred patients engage with the activities prescribed by the navigator?
- e.** Some patients do not attend the prescribed activities as agreed with the navigator. Do you know why patients did not attend the prescribed activities?

PART C OUTCOMES

My last questions are about the effects of the Social Prescribing service on referred patients.

7. Outcomes for service user

a. From your experience, what are the outcomes for patients participating in the Social Prescribing service?

8. Final question

Is there anything else you would like to tell me about the engagement or outcomes for service users?

Thank you for your help today!
(-End of the interview-)

TOPIC GUIDE - NAVIGATOR

Topic Guide version 2A

Name of interviewee:

General Practice:

Date of interview:

Obtaining consent

Thank you for agreeing to take part in this interview. The interview will take about 30-40 minutes. There are no right or wrong answers to my questions. I am interested in your views and experiences. You do not have to answer any question you do not want to. I will record the answers that you give me and the information that you provide will be used in my PhD thesis, reports, and journal articles. Any quotes and information will be anonymised and I will do all that I can to ensure that you cannot be identified in the write-ups. You will be referred to as Navigator (number) when findings are written up for the thesis, reports, and publications. Please remember that participation is voluntary and you may stop this interview at any time without giving any reason.

Before we start, I would like to ask you to sign two copies of the consent form – one for you to keep and one for my research file. Please take time to read the consent form and ask me any questions you might have before you initial each box and sign.

Definition of terms

The social prescribing service in Luton is a pilot programme. You were one of the first navigators involved in the pilot. I would like to ask you questions about your role, and factors that influence the implementation and delivery of the Social Prescribing service in Luton. I am also interested in your views about patient engagement and outcomes for patients. For the purpose of this interview *implementation* is defined as a set of activities and processes designed to put a service (in this case Social Prescribing) into practice. The term *delivery* refers to the actual provision of the Social Prescribing service to primary care patients. For example, in the Social Prescribing service in Luton, referrers (GPs), navigators, and service providers in the third sector have direct contact with primary care patients for the purpose of delivering the Social Prescribing service. Do you have any questions regarding these terms?

(-Start of the interview-)

PART A INTRODUCTION

1. Introduction

- a. Can you tell me a bit about yourself (e.g. background and previous experience)?
- b. Can you tell me about your role in the Social Prescribing service in Luton?
- c. When did you join the Social Prescribing team?
- d. How would you describe the stage of the implementation process of the Social Prescribing service when you joined?
- e. Have you heard about 'Social Prescribing' before you applied for the navigator role?
 - (i) If yes, where?

PART B. IMPLEMENTATION AND DELIVERY

2. Social Prescribing

- a. How would you describe the Social Prescribing service in Luton?

3. Implementation

- a. If you think back to your first days of being a navigator in the SP pilot, do you remember what you felt like and what your first impressions were about the SP service in Luton?

Probes: For example your experience with the medical team and management team you worked with, the organisation of the programme, the clarity of your role, your working space in the general practice

- b. Do you remember how your first weeks were working as one of the first navigators in the Social Prescribing pilot?

- (i) Do you remember what helped you at the beginning to settle down and to perform your role as one of the first navigator?

- (ii) Do you remember what made it difficult for you to perform your role as one of the first navigators at the beginning?

- c. The SP service in Luton is a pilot programme, has your role changed as the programme is progressing?

- (i) If yes, can you tell me about these changes?

- d. As a navigator, you attend regular meetings with different stakeholders to discuss the implementation process of the Social Prescribing service, right?

- (i) From your experience, what has hindered the implementation of the Social Prescribing service in Luton?

(ii) From your experience, what has facilitated the implementation of the Social Prescribing service in Luton?

4. Delivery

- a.** Can you tell me about your working practice (e.g. what would a normal day look like)?
- b.** Are there any challenges or difficulties you face as a navigator?
- c.** What would help you to overcome these challenges?
- d.** What helps you to perform your role as a navigator?
- e.** There are three partners involved in the delivery of the Social Prescribing service:
 - 1. The GP who identifies and refers patients to the service
 - 2. You, the navigator who contacts referred patients, identifies psychosocial needs of service users, and supports access to sources of support
 - 3. Service providers in the third sector who provide activities and services
- f.** Can you tell me about your experience of the delivery of the Social Prescribing service? How does it work in practice (the whole SP pathway)?
 - (i) How do the involved partners communicate?
- g.** What makes it difficult, and what helps, to delivery the Social Prescribing service?
- h.** Which changes would you suggest to improve the delivery of the service?

7. Final question

- a.** Is there anything else you would like to tell me about the implementation and delivery of the Social Prescribing service I have not asked you so far?

PART C SERVICE USER ENGAGEMENT

8. Service user engagement

- a.** In the SP programme in Luton, GPs refer patients to the SP program and the navigators (you) contact the patients to arrange an appointment, right?
 - (i) Do you know why referred patients agree to come to the first appointment with you?
 - (ii) Do you know why referred patients do not agree, and do not come, to the first appointment with you?
- b.** Did it happen before that a referred patient decided not to participate in the Social Prescribing service during- or immediately after- the first appointment with a navigator?
 - (i) If yes, do you know why the patient decided not to engage anymore?
- c.** Do you know why referred patients are willing to participate in the signposted or prescribed activities/services as agreed with the navigators?
- d.** Do you know what stops referred patients from attending agreed activities?

PART D OUTCOMES

9. Outcomes for service user

The last question is about the outcomes for referred patients.

a. What are the outcomes (including both positive and negative ones) for patients who engaged with the Social Prescribing service?

10. Long term outcomes

Patients can attend the prescribed activities for a limited number of weeks (about 12 weeks) as part of the Social Prescribing service. The service ends with a final appointment with you, right?

a. What do you discuss in this appointment?

b. From your experience, do patients continue to do similar activities after being involved in the Social Prescribing service?

(i) Why?/ Why not?

11. Final question

Is there anything else you would like to tell me about the engagement of service users and outcomes of the service?

Thank you for your help today!

(-End of the interview-)

TOPIC GUIDE – MANAGERS AND DECISION-MAKERS

Interview schedule version 2C1 09.11.2016

Name of interviewee:

Date of interview:

Role/ Organisation:

Obtaining consent

Thank you for agreeing to take part in this interview. The interview will take about 30-40 minutes. There are no right or wrong answers to my questions. I am interested in your views and experiences. You do not have to answer any question you do not want to. I will record the answers that you give me and the information that you provide will be used in my PhD thesis, reports, and journal articles. Any quotes and information will be anonymised and I will do all that I can to ensure that you cannot be identified in the write-ups. You will be referred to as Manager (number) when findings are written up for the thesis, reports, and publications. Please remember that participation is voluntary and you may stop this interview at any time without giving any reason.

Before we start, I would like to ask you to sign two copies of the consent form – one for you to keep and one for my research file. Please take time to read the consent form and ask me any questions you might have before you initial each box and sign.

Definition of terms

Social Prescribing is a relatively new service in Luton. You are involved in the implementation/ delivery of the Social Prescribing service in Luton. I would like to ask you questions about your role, and factors that influence the implementation and delivery of the Social Prescribing service. For the purpose of this interview the term *implementation* is defined as a set of activities and processes designed to put a service (in this case Social Prescribing) into practice. The term *delivery* refers to the actual provision of the Social Prescribing service to primary care patients. For example, in the Social Prescribing service in Luton, referrers (GPs), navigators, and service providers in the third sector have direct contact with primary care patients for the purpose of delivering the Social Prescribing service. Do you have any questions regarding these terms?

PART A INTRODUCTION

1. Introduction

- a. Can you tell me about your role in the Social Prescribing service in Luton?
- b. When did you join the Social Prescribing team?

PART B IMPLEMENTATION

2. Social Prescribing

- a. How would you describe the Social Prescribing service in Luton?

3. Implementation

You have been involved in the implementation of the Social Prescribing service in Luton since “*answer 1 b.*”. Now, please try to think back to the time between the first days you became involved with the Social Prescribing service and today.

- a. Can you remember what helped to implement the Social Prescribing service in Luton?
- b. Can you remember what hindered the implementation of the Social Prescribing service?
- c. If the implementation process were to start again from the beginning, what would you do differently and what would you do in the same way?

PART C DELIVERY

3. Delivery

- a. Can you tell me how the Social Prescribing service works in practice?
- b. What helps to deliver the service as intended?
- c. What hinders the delivery of the service as intended?

4. Closing question

- a. Is there anything else you would like to tell me about the implementation and/or delivery of the Social Prescribing service in Luton I have not asked you about?

Thank you for your help today!

(-End of the interview-)

TOPIC GUIDE - SERVICE PROVIDER

Topic Guide version 2D

Name of interviewee:

Organisation:

Date of interview:

Obtaining consent

Thank you for agreeing to take part in this interview. The interview will take about 40 minutes. There are no right or wrong answers to my questions. I am interested in your views and experiences. You do not have to answer any question you do not want to. I will record the answers that you give me and the information that you provide will be used in my PhD thesis, reports, and journal articles. Any quotes and information will be anonymised and I will do all that I can to ensure that you cannot be identified in the write-ups. You will be referred to as Service provider (number) when findings are written up for the thesis, reports, and publications. Please remember that participation is voluntary and you may stop this interview at any time without giving any reason.

Before we start, I would like to ask you to sign two copies of the consent form – one for you to keep and one for my research file. Please take time to read the consent form and ask me any questions you might have before you initial each box and sign.

Social Prescribing is a relatively new service in Luton. You are one of the service providers of the Social Prescribing service. I would like to ask you a few questions about your views and experiences of the service.

(-Start of the interview-)

PART A INTRODUCTION

1. Introduction

a. Can you tell me a bit about your organisation and your role at the organisation?

(i) What kind of activities does “name of the organisation” offer?

(ii) Are you involved in providing activities? Which ones?

(ii) How many employees does the organisation has?

(iii) Is “name of organisation” commissioned by the Luton Borough Council?

PART B IMPLEMENTATION AND DELIVERY

2. Social Prescribing

a. How would you describe the Social Prescribing service in Luton?

3. Implementation

a. How and when did you first hear about the Social Prescribing service in Luton?

b. Do you remember what you first felt and thought when you heard about it?

c. Why did you want to get involved with the Social Prescribing service in Luton?

d. Once you decided to become involved, what happened next?

(i) How did you experience this process?

(ii) If not covered - Can you tell me about your experience with the accreditation process for the Social Prescribing service?

4. Delivery

In the Social Prescribing service in Luton, GPs identify and refer patients to the service. A navigator contacts referred patients to arrange a meeting to assess their non-medical needs and to connect them with sources of support. One of the organisations that offer activities/services for referred patients is “*name of organisation*”

a. Can you tell me about your experience of being involved in the Social Prescribing service?

How does it work in practice?

Probe (if not covered)

(i) When a referred patient attends “name of the activity”, do you know that they attend the activity/course/class as part of the Social Prescribing service?

(ii) How?

(iii) Does it make a difference for you? Why?/ Why not?

- (iv) Do you get paid for the service you provide for each referred patient?
- (v) How does the reimbursement process work?

PART C Continuity of activities

5. Long term outcomes

Patients can attend the prescribed activities for a limited number of weeks (about 12 weeks) as part of the Social Prescribing service in Luton.

- a.** Do you know whether people who were initially referred through the Social Prescribing service continue to attend “name of the activity” or other activities beyond the service?

Thank you for your help today!

(-End of the interview-)

TOPIC GUIDE – SERVICE USER

Version 3A 09.11.2016

First name of interviewee:

Identification number:

M/F:

Date of interview:

Obtaining consent

Hello, my name is Julia and I am a researcher at University of Bedfordshire. Thank you for agreeing to take part in this interview. The interview will take about one hour. There are no right or wrong answers to my questions. I am interested in your views and experiences. You do not have to answer any question you do not want to. I will record the answers that you give me and the information that you provide will be used in my PhD thesis and possibly in journal articles and reports. Any quotes and information that I use will be anonymised, and I will do all that I can to ensure that you cannot be identified in the write-ups. You will be referred to as Service users (number) when findings are written up for the thesis, reports, and publications. Please remember that participation is voluntary and you may stop this interview at any time without giving any reason.

Before we start, I would like to ask you to sign two copies of the consent form – one for you to keep and one for my research file. Please take time to read the consent form and ask me any questions you might have before you initial each box and sign.

Definition of Social Prescribing

Social Prescribing is way of linking primary care patients, who visit their GP practice, with non-medical sources of support in the community. I would like to ask you a few questions about your views and experiences with the Social Prescribing service in Luton.

(-Start of the interview-)

PART A INTRODUCTION

1. Introduction

a. Can you tell me a little about yourself?

If not covered ask for:

- Age
- Ethnicity
- Employment status
- Marital status

PART B SERVICE USER ENGAGEMENT

2. Social Prescribing

a. How would you describe the Social Prescribing service in Luton?

3. Experience

a. Can you tell me a bit about your experience with the Social Prescribing service?

4. GP referral to the Social Prescribing service

- a.** Do you know why your GP referred you to the Social Prescribing service?
- b.** Can you remember when your GP referred you to the Social Prescribing service?
- c.** Do you remember what your GP told you about Social Prescribing before referring you to the service?
- d.** What did you feel when your GP suggested it to you?
- e.** Why did you agree to be referred to the Social Prescribing service?

5. Navigator contact and appointment

After your GP referred you to the Social Prescribing service, a navigator contacted you, right?

- a.** What did you think and feel when the navigator contacted you to arrange an appointment?
- b.** Did you go to the appointment and did you meet the navigator?
 - (i) Why did you go? Why did not you go/ did not meet the navigator?
- c.** Can you tell me a bit about your experience of the appointments with the navigator? What happened in the meeting(s)?
- d.** How would you describe the relationship between you and the navigator?

(i) How did your relationship with the navigator affect your experience with the Social Prescribing service?

6. Prescribed services/activities

a. In the appointment, you and the navigator agreed on activities or services you could go to, what were these?

b. How did you feel about these activities/services when they were suggested to you?

c. Did you attend activities/services as agreed with the navigator, for example every week?

(i) Why did you attend the services/activities as agreed? Why not?

d. Can you tell me a bit about your experience with the activities/services you attended?

7. Final question

a. Is there anything else that influenced your engagement (or non-engagement) with the Social Prescribing service that I have not asked you about?

PART C OUTCOMES FOR SERVICE USERS

8. Outcomes for service users

a. Have you noticed any changes in your wellbeing since being referred to the Social Prescribing service?

b. Have you noticed any other changes [*for example changes related to referred activities/services*] since being referred to the Social Prescribing service?

9. Any other outcomes/consequences

a. Is there anything else that changed since you have been involved with the Social Prescribing service that I have not asked you about?

10. Long term outcomes

You can attend the prescribed service for a limited number of weeks as part of the Social Prescribing service.

a. Did you continue (*or are you planning to continue*) to do similar activities after your participation in the Social Prescribing service?

(i) Why? Why not?

11. Final open question

a. Is there anything else you would like to tell me I have not asked you about?

Thank you very much for your help today.

(-End of the interview-)

Appendix 20: Secondary data for ethnicity of service users

Table 35: Reported ethnicities of service users referred to the Luton social prescribing programme (secondary data)

African
 African Carribbean
 Asian
 Asian Bangladeshi
 Asian British Pakistani
 Asian Kashmiri
 Asian Pakistani
 Assian Arab
 bangadeshi
 Bangladeshi
 bengali
 Bengali
 Black african
 Black African
 black caribbean
 Black Caribbean
 British
 British Pakistani
 Caribbean
 Caucasian
 Eastern European
 German European
 indian
 Indian
 Iranian
 Irish
 Kashmiri Pakistani
 Mixed british
 Mixed Carribean
 North African
 Not stated
 Other
 other Asian
 other black background
 other mixed
 Other white
 Other white background
 Pakinstani
 pakistani
 Pakistani
 pakistani british
 Polish
 Punjabi Indian
 Russian
 Serbian
 Somali Black African
 Somalian
 Sottish
 South African
 south asian
 unknown

Appendix 21: Secondary data for reasons of referrals to social prescribing

Table 36: Reported reasons for referrals to the Luton social prescribing programme (secondary data)

5 young children	A	A,D
A	A,D	ADLI
ADLI	ADLI	Alcoholism
Alcohol	Alcohol	anxiety/depression
Already seeing Community mental health team	ALDI	Asthma
anger management	anxiety depression	benefits
Arthritis	benefits	bereavement
Asthma	benefits/finance	bereavement
Autism	bereavement support/social isolation	bereavment
Benefits	isolation	C
bereavement / potential learning difficulty	Bereavement/low mood	C,ADLI
Blue Badge	blind community support	carer
BP	breast cancer	Chronic Fatigue
C	C	Confidence building
Cancer	career	CVD
Career seeking information around community exercises	Carer	D
carer/supports family	COPD	D,C
children in foster care	COPD, MH,SI,	D,I
confidence building	D	D,I,L
coordinate support letter to support PIP- had stroke does not talk much, family interpret	D & Kidney Disease	D,L
COPD	D, Weight loss	depression
court case with family	depression	Di
CVD	Di	diabetes
D	Di, C	Diabetes
Dementia	Di, FE	Employability / work support
Di	DI, FE	failed PIP application
Di,ADLI	Diabetes, anxiety	FE
diabetes	diabetic	finance/housing
diabetes/high BP	Diabetic	financial management
DRC referral done on behalf of the Nurse	Disability support	financial problems
Drugs	disability support around the family	Financial support
Employability	disability/benefits support	fininace
employment	Divorce	frailty list
Employment / work	DV support	Gambling
Fall	employment support	housed in Luton from London
FE	Exercise referral	housing
Fibromyalgia	FE	Housing
Finance	finanacial support	housing/finance
Glaucoma	Getting into drugs	I,L
home sick	High BP/Diabetes	improved wellbeing
Housing	housing	increase physical activity
HOUSING	Housing	isolation
Hypertension	housing support	learning difficulty
I	housing, finance	long term sick
I,L	increased stress	low income/poor living
Inappropriate referral- back to GP	Increased stress	low mood
	job seeking	low mood/bereavment
	Learning difficulty	MH
	Looking to increase physical	mild learning difficulty
		Mild learning difficulty
		motivation

Abbreviations

A: Anxiety	MH: Mental health issues
C: Carer	
D: Depression	
Di: Depression	
EF: Fitness and exercise	
I: Isolation	
L: Loneliness	

Appendix 22: Secondary data on reported barriers to adherence to the social prescribing programme

Table 37: Reported barriers to adherence to the social prescribing programme (secondary data)

MH, NC, A, W	A, MH, C
MH, P	A, NC,
MH, P, A	A, Finance, transport
MH, P, A, C	alcohol
MH, P, A, IA	C
MH, P, A, MA, NC, IA	C, P
MH, P, A, NC, IA	C, P, MH
MH, P, A, W, M	C. P, MH
MH, P, C, IA	Caring for her father and I
MH, P, C, IA, A	available to give him his
MH, P, IA	medication
MH, P, IA, A	Ch
MH, P, IA, C,	CH
MH, P, IA, NC	CH WK
MH, P, NC, IA	Health condition
MH, P, NC, IA, M, A	IA
MH, A	IA, Ch
MH, A,	IA, MH,
MH, A, T, Transport	IA, NC, C, P
MH, CH, Finance	IA, NC, P
MH, CH, P, A, IA	IA, P
MH, finance	IA, P,
MH, Finance	IA, P, MH
MH, Financial	IA, P, MH, A, NC
MH, M,	IA, P, travel, M
MH, M, TA	IA, MH, M, A
MH, MI	IA, MH, W, A
MH, MI, CH	IA, P
MH, P, A	learning difficulty
MH, T, ch	Learning difficulty, A
MH, T, IA, A	M
MH, T, WK	M, MH
MH, T, WK, MI	M, P, A, IA
MI	M/H
Mobility	MA
Multiple health issues - illness	MH
/ renal crisis	MH,
NC	MH, A
NC, C, W	MH, A, IA
NC, MH	MH, A, IA, P
NC, MH, P, IA	MH, A, NC,
NC, P, IA	MH, A, P, NC
NC, W, MH	MH, C
P	MH, C, A, NC
P, A, MA, NC, IA, MH	MH, C, NC
P, A, IA, MH	MH, C, NC, P
P, A, M, MH	MH, IA
P, A, MH	MH, IA,
P, A, IA, MA	MH, IA, A, NC, P
P, A, IA, MA, M	MH, Language, Transport, I
P, IA	MH, M, Ch, P, MA, IA
P, IA,	MH, Mobility issues. Pain
	MH. NC

Abbreviations

A: Alone, no one to go with	M: Money	P: Pain
Ch/C: Children	MH: Mental health issues	T: Time
I/A: Immobility/ Access	NC: Non compliant	WK: Work

Appendix 23: Distribution of difference scores for Walking, Moderate, Vigorous, and Total MET-minutes/week

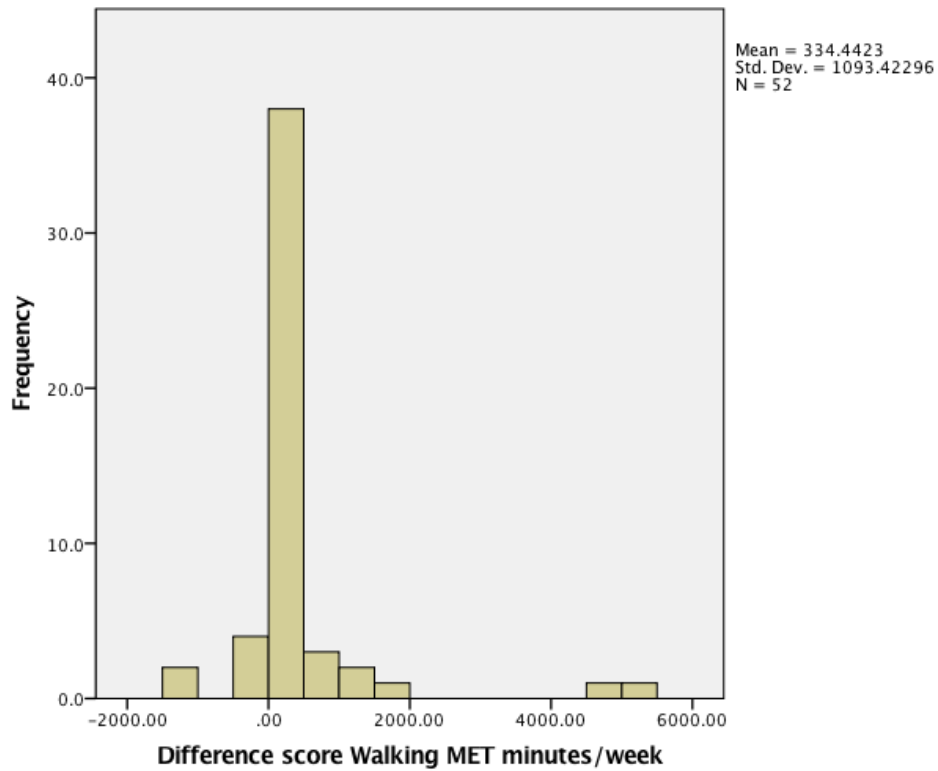


Figure 19: Histogram of Walking MET minutes/week difference score distribution (N=52)

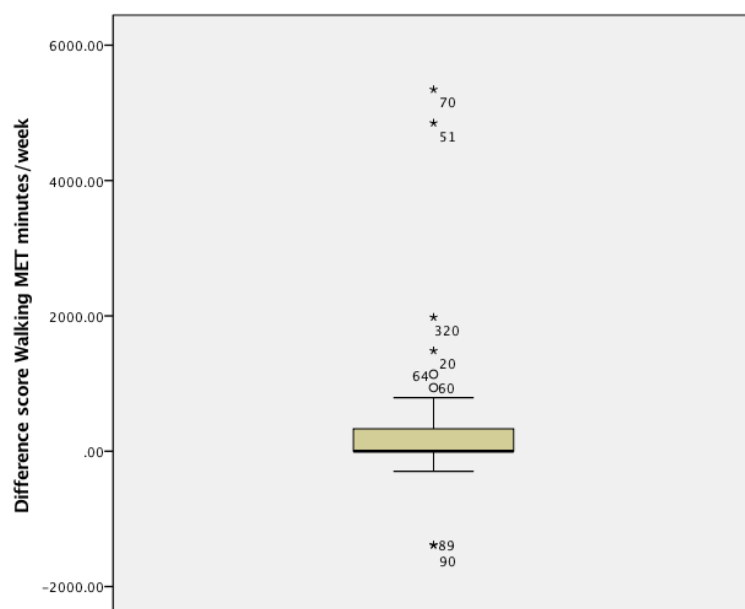


Figure 20: Box and whisker plot of Walking MET minutes/week difference score distribution (N=52)

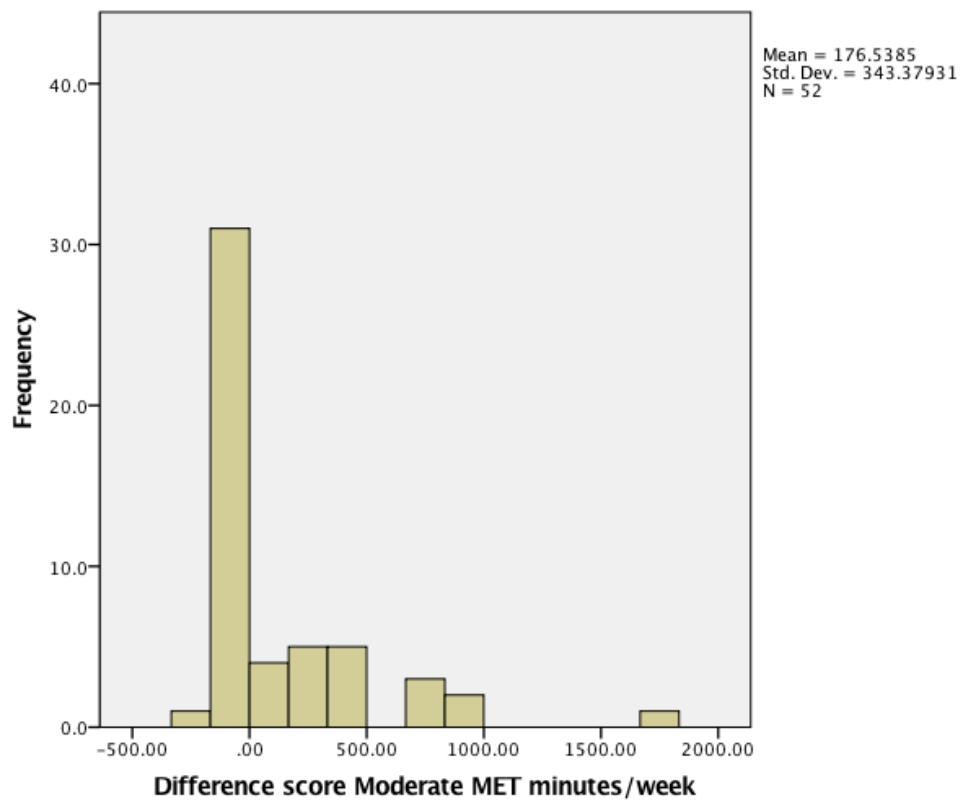


Figure 21: Histogram of Moderate MET minutes/week difference score distribution (N=52)

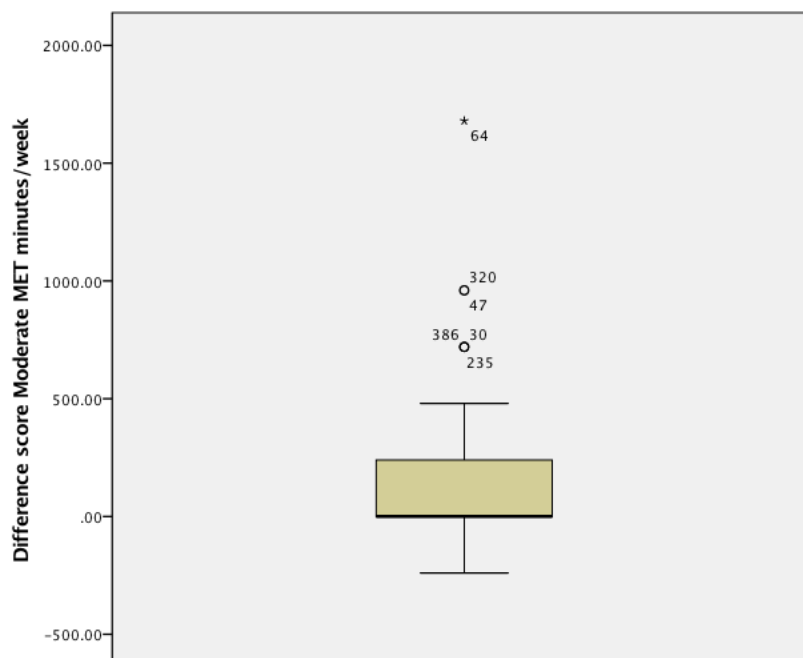


Figure 22: Box and whisker plot of Moderate MET minutes/week difference score distribution (N=52)

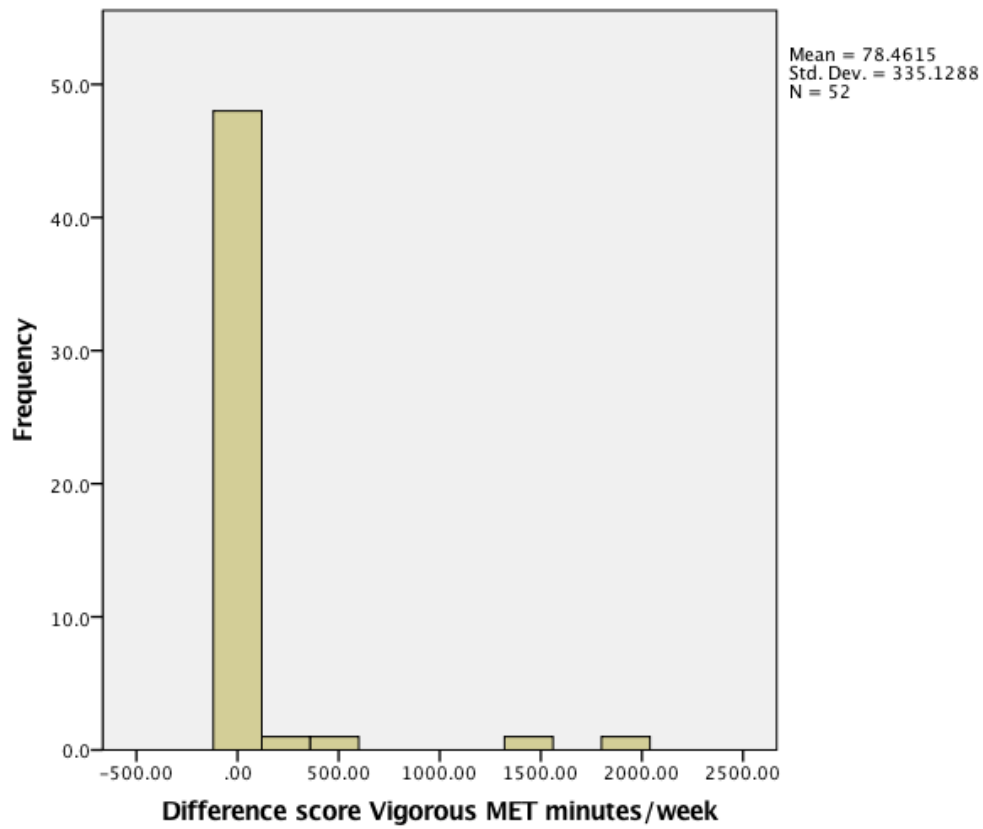


Figure 23: Histogram of Vigorous MET minutes/week difference score distribution (N=52)

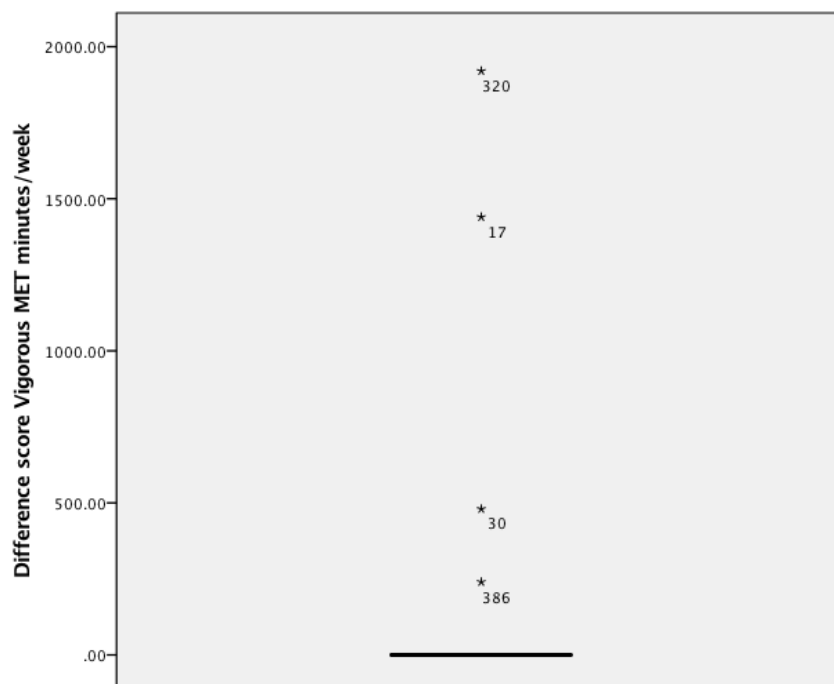


Figure 24: Box and whisker plot of Vigorous MET minutes/week difference score distribution (N=52)

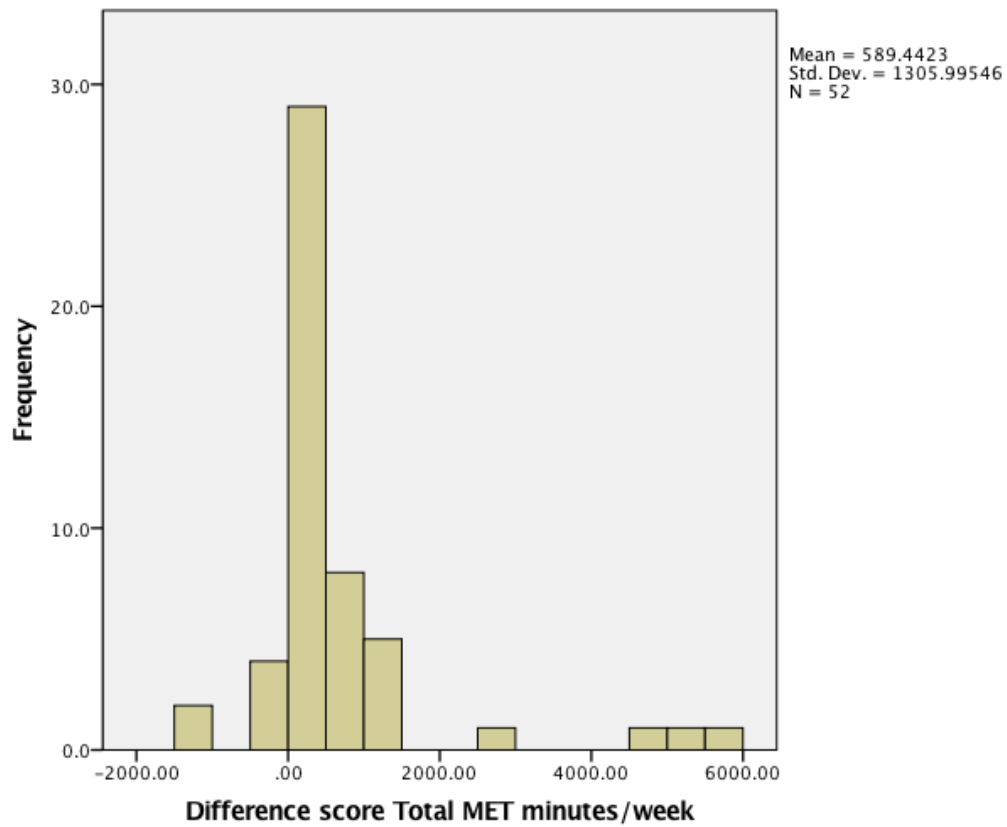


Figure 25: Histogram of Total MET minutes/week difference score distribution (N=52)

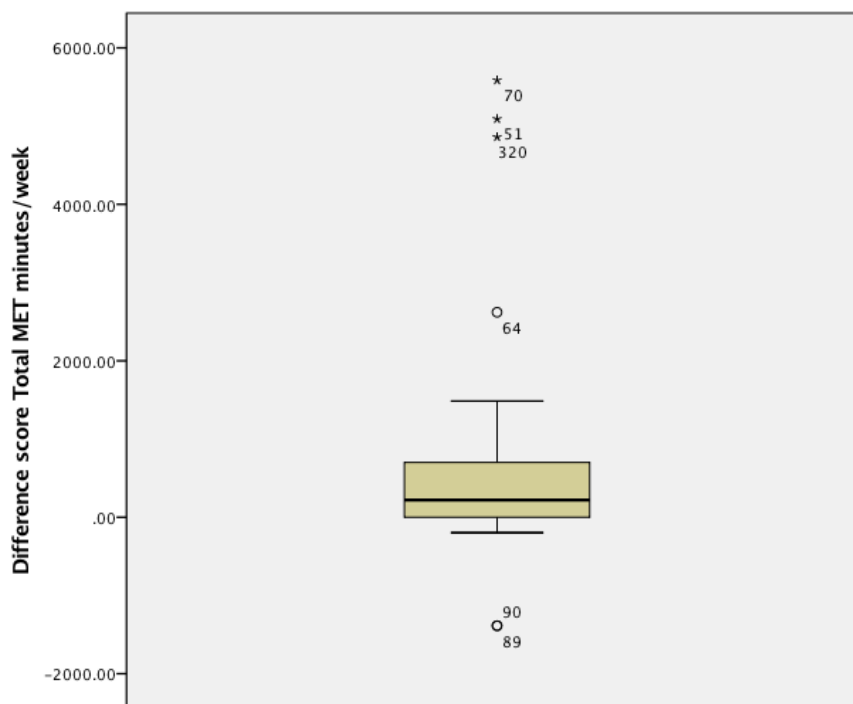


Figure 26: Box and whisker plot of Total MET minutes/week difference score distribution (N=52)

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